UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.**

For the quarterly period ended June 30, 2021

or

☐ **TRANSITION REPORTS PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.**

For the transition period from to

Commission File Number: 001-35068

ACELRX PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**41-2193603**
(State or other jurisdiction of incorporation or organization)	**(IRS Employer Identification No.)**

25821 Industrial Boulevard, Suite 400
Hayward, CA 94545
(650) 216-3500
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class:	**Trading symbol(s)**	**Name of Each Exchange on Which registered:**
Common Stock, $0.001 par value	**ACRX**	**The Nasdaq Global Market**

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.:

Large accelerated filer	☐	Accelerated filer	
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging growth company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Exchange Act Rule 12b-2) Yes ☐ No ☒

As of August 11, 2021, the number of outstanding shares of the registrant's common stock was 119,179,806.

ACELRX PHARMACEUTICALS, INC.

QUARTERLY REPORT ON FORM 10-Q FOR THE QUARTER ENDED JUNE 30, 2021

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Unless the context indicates otherwise, the terms "AcelRx," "AcelRx Pharmaceuticals," "we," "us" and "our" refer to AcelRx Pharmaceuticals, Inc., and its consolidated subsidiaries. "DZUVEO" is a trademark, and "ACELRX", "DSUVIA" and "Zalviso" are registered trademarks, all owned by AcelRx Pharmaceuticals, Inc. This report also contains trademarks and trade names that are the property of their respective owners.

Forward-Looking Statements

This Quarterly Report on Form 10-Q, or Form 10-Q, contains "forward-looking statements" within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, which are subject to the "safe harbor" created by that section. The forward-looking statements in this Form 10-Q are contained principally under "Part I. Financial Information - Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Part II. Other Information - Item 1A. Risk Factors". In some cases, you can identify forward-looking statements by the following words: "may," "will," "could," "would," "should," "expect," "intend," "plan," "anticipate," "believe," "estimate," "predict," "project," "potential," "continue," "ongoing" or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. These statements involve risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Form 10-Q, we caution you that these statements are based on a combination of facts and factors currently known by us and our projections of the future, about which we cannot be certain. Many important factors affect our ability to achieve our objectives, including:

- the accuracy of our estimates regarding the sufficiency of our cash resources, future revenues, expenses, capital requirements and needs for additional financing, and our ability to obtain additional financing;
- the uncertainties and impact arising from the worldwide COVID-19 pandemic, including restrictions on the ability of our sales force to contact and communicate with target customers and resulting delays and challenges to our commercial sales of DSUVIA® (sufentanil sublingual tablet, 30 mcg);
- our success in commercializing DSUVIA in the United States, including the marketing, sales, and distribution of the product, whether alone or with contract sales organizations and other collaborators;
- our ability to satisfactorily comply with FDA regulations concerning the advertising and promotion of DSUVIA, including receiving a close out letter resolving the concerns raised by FDA in the warning letter delivered to us on February 11, 2021;
- the size and growth potential of the markets for DSUVIA, and Zalviso® (sufentanil sublingual tablet system), if approved in the United States, and our ability to serve those markets;
- our ability to maintain regulatory approval of DSUVIA in the United States, including effective management of and compliance with the DSUVIA Risk Evaluation and Mitigation Strategies, or REMS, program;
- acceptance of DSUVIA by physicians, patients and the healthcare community, including the acceptance of pricing and placement of DSUVIA on payers' formularies;
- the integration and performance of any assets or businesses we acquire;
- our ability to develop and commercialize products and product candidates that we in-license;
- our ability to develop sales and marketing capabilities in a timely fashion, whether alone through recruiting qualified employees, by engaging a contract sales organization, or with potential future collaborators;
- successfully establishing and maintaining commercial manufacturing with third parties;
- our ability to manage effectively, and the impact of any costs associated with, potential governmental investigations, inquiries, regulatory actions or lawsuits that may be brought against us;
- continued demonstration of an acceptable safety profile of DSUVIA;
- effectively competing with other medications for the treatment of moderate-to-severe acute pain in medically supervised settings, including IV-opioids and any subsequently approved products;
- our ability to manufacture and supply DZUVEO® to Laboratoire Aguettant, or Aguettant, in accordance with their forecasts and the License and Commercialization Agreement, or DZUVEO Agreement, with Aguettant;
- the status of the DZUVEO Agreement or any other future potential collaborations, including potential milestones and revenue share payments under the DZUVEO Agreement;
- our, or Aguettant's, ability to maintain regulatory approval of DZUVEO in the European Union, or EU;
- our ability to timely and efficiently close-out our relationship with Grünenthal GmbH, or Grünenthal, following the termination of our Collaboration and License Agreement and the Manufacture and Supply Agreement;
- our ability to fulfill our obligations under the Purchase and Sale Agreement with SWK Funding, LLC, or SWK, (assignee of PDL BioPharma, Inc., or PDL) including our obligation to use commercially reasonable efforts to negotiate a replacement license agreement for Zalviso with a third party;

- our ability to successfully execute the pathway towards a resubmission of the Zalviso New Drug Application, or NDA, and subsequently obtain and maintain regulatory approval of Zalviso in the United States and comply with any related restrictions, limitations, and/or warnings in the label of Zalviso, if approved;
- the outcome of any potential FDA Advisory Committee meeting held for Zalviso;
- our ability to successfully commercialize Zalviso, if approved in the United States;
- the rate and degree of market acceptance of Zalviso, if approved in the United States;
- our ability to obtain adequate government or third-party payer reimbursement;
- our ability to attract additional collaborators with development, regulatory and commercialization expertise;
- our ability to successfully retain our key commercial, scientific, engineering, medical or management personnel and hire new personnel as needed;
- regulatory developments in the United States and foreign countries;
- the performance of our third-party suppliers and manufacturers, including any supply chain impacts or work limitations resulting from shelter-in-place orders related to COVID-19;
- the success of competing therapies that are or become available;
- our liquidity and capital resources; and
- our ability to obtain and maintain intellectual property protection for DSUVIA/DZUVEO and Zalviso.

In addition, you should refer to “Part II. Other Information - Item 1A. Risk Factors” in this Form 10-Q for a discussion of these and other important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Form 10-Q will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. Also, forward-looking statements represent our estimates and assumptions only as of the date of this Form 10-Q. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

AcelRx Pharmaceuticals, Inc.

Condensed Consolidated Balance Sheets
(In thousands, except share data)

	June 30, 2021 (unaudited)	December 31, 2020[1]
Assets		
Current Assets:		
Cash and cash equivalents	$ 26,327	$ 27,274
Short-term investments	28,998	15,612
Accounts receivable, net	104	635
Inventories, net	1,363	1,626
Prepaid expenses and other current assets	2,178	1,683
Total current assets	58,970	46,830
Operating lease right-of-use assets	4,607	3,150
Property and equipment, net	15,939	15,659
Other assets	70	656
Total Assets	$ 79,586	$ 66,295
Liabilities and Stockholders' Deficit		
Current Liabilities:		
Accounts payable	$ 1,941	$ 2,737
Accrued and other liabilities	3,980	5,045
Long-term debt, current portion	8,764	8,735
Operating lease liabilities, current portion	503	1,118
Total current liabilities	15,188	17,635
Long-term debt, net of current portion	9,374	13,140
Operating lease liabilities, net of current portion	4,115	2,606
Liability related to the sale of future royalties, net of current portion	86,770	88,365
Other long-term liabilities	128	299
Total liabilities	115,575	122,045
Commitments and Contingencies		
Stockholders' Deficit:		
Common stock, $0.001 par value—200,000,000 shares authorized as of June 30, 2021 and December 31, 2020; 119,179,806 and 98,812,008 shares issued and outstanding as of June 30, 2021 and December 31, 2020, respectively	119	98
Additional paid-in capital	421,184	382,637
Accumulated deficit	(457,292)	(438,485)
Total stockholders' deficit	(35,989)	(55,750)
Total Liabilities and Stockholders' Deficit	$ 79,586	$ 66,295

[1] The condensed consolidated balance sheet as of December 31, 2020 has been derived from the audited financial statements as of that date included in the Company's Annual Report on Form 10-K for the year ended December 31, 2020.

See notes to condensed consolidated financial statements.

AcelRx Pharmaceuticals, Inc.

Condensed Consolidated Statements of Comprehensive Loss
(Unaudited)
(In thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	**2020**	**2021**	**2020**
Revenue:				
Product sales	$ 392	$ 303	$ 843	$ 577
Contract and other collaboration	51	2,621	111	2,733
Total revenue	443	2,924	954	3,310
Operating costs and expenses:				
Cost of goods sold	1,040	1,370	2,080	2,881
Research and development	724	813	1,693	2,225
Selling, general and administrative	8,694	7,575	16,338	20,886
Total operating costs and expenses	10,458	9,758	20,111	25,992
Loss from operations	(10,015)	(6,834)	(19,157)	(22,682)
Other income:				
Interest expense	(614)	(872)	(1,286)	(1,727)
Interest income and other (expense) income, net	(16)	270	60	205
Non-cash interest income on liability related to future sale of royalties	799	834	1,581	1,677
Total other income	169	232	355	155
Net loss before income taxes	(9,846)	(6,602)	(18,802)	(22,527)
Provision for income taxes	(5)	(4)	(5)	(4)
Net loss	$ (9,851)	$ (6,606)	$ (18,807)	$ (22,531)
Comprehensive loss	$ (9,851)	$ (6,606)	$ (18,807)	$ (22,531)
Net loss per share of common stock, basic and diluted	$ (0.08)	$ (0.08)	$ (0.16)	$ (0.28)
Shares used in computing net loss per share of common stock, basic and diluted – See Note 11	119,120,040	80,661,853	116,204,492	80,359,679

See notes to condensed consolidated financial statements.

AcelRx Pharmaceuticals, Inc.

Condensed Consolidated Statements of Stockholders' (Deficit) Equity
(Unaudited)
(in thousands, except share data)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount			
Balance as of December 31, 2020	98,812,008	$ 98	$ 382,637	$ (438,485)	$ (55,750)
Stock-based compensation	—	—	1,089	—	1,089
Restricted stock units vested	404,172	—	—	—	—
Tax payments related to shares withheld for restricted stock units vested	—	—	(249)	—	(249)
Net proceeds from issuance of common stock in connection with equity financings	19,701,562	20	36,340	—	36,360
Issuance of common stock upon ESPP purchase	183,132	—	192	—	192
Issuance of common stock upon exercise of stock options	2,125	—	2	—	2
Net loss	—	—	—	(8,956)	(8,956)
Balance as of March 31, 2021	119,102,999	118	420,011	(447,441)	(27,312)
Stock-based compensation	—	—	1,172	—	1,172
Restricted stock units vested	74,438	—	—	—	—
Issuance of common stock upon exercise of stock options	2,369	1	1	—	2
Net loss	—	—	—	(9,851)	(9,851)
Balance as of June 30, 2021	119,179,806	$ 119	$ 421,184	$ (457,292)	$ (35,989)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount			
Balance as of December 31, 2019	79,573,101	$ 79	$ 356,609	$ (398,106)	$ (41,418)
Stock-based compensation	—	—	1,146	—	1,146
Restricted stock units vested	216,399	—	—	—	—
Tax payments related to shares withheld for restricted stock units vested	—	—	(86)	—	(86)
Net proceeds from issuance of common stock in connection with equity financings	431,800	1	783	—	784
Issuance of common stock upon ESPP purchase	194,451	—	218	—	218
Net loss	—	—	—	(15,925)	(15,925)
Balance as of March 31, 2020	80,415,751	80	358,670	(414,031)	(55,281)
Stock-based compensation	—	—	1,090	—	1,090
Restricted stock units vested	29,434	—	—	—	—
Net proceeds from issuance of common stock in connection with equity financings	445,000	—	665	—	665
Net loss	—	—	—	(6,606)	(6,606)
Balance as of June 30, 2020	80,890,185	$ 80	$ 360,425	$ (420,637)	$ (60,132)

See notes to condensed consolidated financial statements.

AcelRx Pharmaceuticals, Inc.

Condensed Consolidated Statements of Cash Flows
(Unaudited)
(In thousands)

	Six Months Ended June 30,	
	2021	**2020**
Cash flows from operating activities:		
Net loss	$ (18,807)	$ (22,531)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash royalty revenue related to royalty monetization	(83)	(121)
Non-cash interest income on liability related to royalty monetization	(1,581)	(1,677)
Depreciation and amortization	1,029	979
Non-cash interest expense related to debt financing	430	558
Stock-based compensation	2,261	2,236
Other	(61)	341
Changes in operating assets and liabilities:		
Accounts receivable	531	237
Inventories	143	277
Prepaid expenses and other assets	(277)	94
Accounts payable	(65)	675
Accrued liabilities	(963)	(1,779)
Operating lease liabilities	(563)	(442)
Deferred revenue	(49)	(2,901)
Net cash used in operating activities	(18,055)	(24,054)
Cash flows from investing activities:		
Purchase of property and equipment	(1,615)	(170)
Purchase of investments	(38,201)	(28,807)
Proceeds from maturities of investments	24,784	58,555
Net cash (used in) provided by investing activities	(15,032)	29,578
Cash flows from financing activities:		
Payment of long-term debt	(4,167)	—
Net proceeds from issuance of common stock in connection with equity financings	36,360	1,449
Net proceeds from issuance of common stock through equity plans	196	218
Payment of employee tax obligations related to vesting of restricted stock units	(249)	(86)
Net cash provided by financing activities	32,140	1,581
Net (decrease) increase in cash and cash equivalents	(947)	7,105
Cash and cash equivalents—Beginning of period	27,274	14,684
Cash and cash equivalents—End of period	$ 26,327	$ 21,789

See notes to condensed consolidated financial statements.

1. Organization and Summary of Significant Accounting Policies

The Company

AcelRx Pharmaceuticals, Inc., or the Company or AcelRx, was incorporated in Delaware on July 13, 2005 as SuRx, Inc., and in January 2006, the Company changed its name to AcelRx Pharmaceuticals, Inc. The Company's operations are based in Hayward, California.

AcelRx is a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for use in medically supervised settings. DSUVIA® (known as DZUVEO® in Europe) and Zalviso® are both focused on the treatment of acute pain, and each utilize sufentanil, delivered via a non-invasive route of sublingual administration, exclusively for use in medically supervised settings. On November 2, 2018, the U.S. Food and Drug Administration, or FDA, approved DSUVIA for use in adults in a certified medically supervised healthcare setting, such as hospitals, surgical centers, and emergency departments, for the management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. The commercial launch of DSUVIA in the United States occurred in the first quarter of 2019. In June 2018, the European Commission, or EC, granted marketing approval of DZUVEO for the management of acute moderate to severe pain in adults in medically monitored settings. AcelRx is further developing a distribution capability and commercial organization to continue to market and sell DSUVIA in the United States. In geographies where AcelRx decides not to commercialize products by itself, the Company may seek to out-license commercialization rights. The Company currently intends to commercialize and promote DSUVIA/DZUVEO outside the United States with one or more strategic partners, and, in July 2021, entered into a License and Commercialization Agreement with Laboratoire Aguettant, or Aguettant, for Aguettant to commercialize DZUVEO in the European Union, Norway, Iceland, Liechtenstein, Andorra, Vatican City, Monaco, Switzerland and the United Kingdom (see Note 12 "Subsequent Events" below). The timing of the resubmission of the Zalviso new drug application, or NDA, is in part dependent upon the finalization of the FDA's new opioid approval guidelines and process. AcelRx intends to seek regulatory approval for Zalviso in the United States and, if successful, potentially promote Zalviso either by itself or with strategic partners. Zalviso is approved in Europe and was commercialized by Grünenthal GmbH, or Grünenthal, through May 12, 2021 (see *Termination of Grünenthal Agreements* below). In July 2021, the Company also entered into a separate License and Commercialization Agreement with Aguettant pursuant to which the Company obtained the exclusive right to develop and, subject to FDA approval, commercialize in the United States (i) an ephedrine pre-filled syringe containing 10 ml of a solution of 3 mg/ml ephedrine hydrochloride for injection, and (ii) a phenylephrine prefilled syringe containing 10 ml of a solution of 50 mcg/ml phenylephrine hydrochloride for injection (see Note 12 "Subsequent Events" below).

The Company has incurred recurring operating losses and negative cash flows from operating activities since inception. As of June 30, 2021 and December 31, 2020, the Company had cash, cash equivalents and short-term investments of $55.3 million and $42.9 million, respectively. Based on the Company's current operating plans and projections, the Company expects that its existing cash, cash equivalents and short term investments will be sufficient to fund operations for at least one year from the date this Quarterly Report on Form 10-Q is filed with the United States Securities and Exchange Commission, or SEC. Although Zalviso was approved for sale in Europe on September 18, 2015, the Company sold the majority of the royalty rights and certain commercial sales milestones it is entitled to receive under the Amended License Agreement (defined below) with Grünenthal to PDL BioPharma, Inc., or PDL, in a transaction referred to as the Royalty Monetization. On August 31, 2020, PDL announced it sold its royalty interest for Zalviso to SWK Funding, LLC, or SWK. In consideration of the termination of the Amended License Agreement, under the Royalty Monetization, the Company must use commercially reasonable efforts to negotiate a replacement license agreement, or New Arrangement, with a third party. The Company expects to continue to incur operating losses and negative cash flows until such time as DSUVIA has gained market acceptance and generated significant revenues.

DSUVIA/DZUVEO

DSUVIA, known as DZUVEO in Europe, approved by the FDA in November 2018 and granted marketing approval by the EC in June 2018, is indicated for use in adults in a certified medically supervised healthcare setting, such as hospitals, surgical centers, and emergency departments, for the management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. DSUVIA was designed to provide rapid analgesia via a non-invasive route and to eliminate dosing errors associated with IV administration. DSUVIA is a single-strength solid dosage form administered sublingually via a single-dose applicator, or SDA, by healthcare professionals. Sufentanil is an opioid analgesic currently marketed for intravenous, or IV, and epidural anesthesia and analgesia. The sufentanil pharmacokinetic profile when delivered sublingually avoids the high peak plasma levels and short duration of action observed with IV administration.

DSUVIA was approved with a Risk Evaluation and Mitigation Strategy, or REMS, which restricts distribution to certified medically supervised healthcare settings in order to prevent respiratory depression resulting from accidental exposure. DSUVIA is only distributed to facilities certified in the DSUVIA REMS program following attestation by an authorized representative to comply with appropriate dispensing and use restrictions of DSUVIA. To become certified, a healthcare setting is required to train their healthcare professionals on the proper use of DSUVIA and have the ability to manage respiratory depression. DSUVIA is not available in retail pharmacies or for outpatient use. As part of the REMS program, the Company monitors distribution and audits wholesalers' data, evaluates proper usage within the healthcare settings and monitors for any diversion and abuse. AcelRx will de-certify healthcare settings that are non-compliant with the REMS program.

Zalviso

Zalviso delivers 15 mcg sufentanil sublingually through a non-invasive delivery route via a pre-programmed, patient-controlled analgesia, or PCA, system. Zalviso is approved in Europe and is in late-stage development in the United States. The Company had initially submitted to the FDA an NDA seeking approval for Zalviso in September 2013 but received a complete response letter, or CRL, on July 25, 2014. Subsequently, the FDA requested an additional clinical study, IAP312, designed to evaluate the effectiveness of changes made to the functionality and usability of the Zalviso device and to take into account comments from the FDA on the study protocol. In the IAP312 study, for which top-line results were announced in August 2017, Zalviso met safety, satisfaction and device usability expectations. These results will supplement the three Phase 3 trials already completed in the Zalviso NDA resubmission.

Termination of Grünenthal Agreements

On December 16, 2013, AcelRx and Grünenthal entered into a Collaboration and License Agreement, or the License Agreement, which was amended effective July 17, 2015 and September 20, 2016, or the Amended License Agreement, which granted Grünenthal rights to commercialize the Zalviso PCA system, or the Product, in the 28 European Union, or EU, member states, at the time of the agreement, plus Switzerland, Liechtenstein, Iceland, Norway and Australia (collectively, the Zalviso Territory) for human use in pain treatment within, or dispensed by, hospitals, hospices, nursing homes and other medically supervised settings, (collectively, the Field). In September 2015, the EC granted marketing approval for the marketing authorization application, or MAA, previously submitted to the EMA, for Zalviso for the management of acute moderate-to-severe post-operative pain in adult patients. On December 16, 2013, AcelRx and Grünenthal, entered into a Manufacture and Supply Agreement, or the MSA, and together with the License Agreement, the Agreements. Under the MSA, the Company exclusively manufactured and supplied the Product to Grünenthal for the Field in the Zalviso Territory. On July 22, 2015, the Company and Grünenthal amended the MSA, or the Amended MSA, effective as of July 17, 2015. The Amended MSA and the Amended License Agreement are referred to as the Grünenthal Agreements.

On May 18, 2020, the Company received a notice from Grünenthal that it had exercised its right to terminate the Grünenthal Agreements, effective November 13, 2020. The terms of the Grünenthal Agreements were extended to May 12, 2021 to enable Grünenthal to sell down its Zalviso inventory, a right it had under the Grünenthal Agreements. The rights to market and sell Zalviso in the Zalviso Territory reverted back to the Company on May 12, 2021.

Principles of Consolidation

The Condensed Consolidated Financial Statements include the accounts of the Company and its wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation. Refer to Note 7 "Liability Related to Sale of Future Royalties" for additional information.

Reclassifications

Certain prior period amounts in the Condensed Consolidated Financial Statements have been reclassified to conform to the current period's presentation.

Basis of Presentation

The accompanying unaudited Condensed Consolidated Financial Statements have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP, for interim financial information and the rules and regulations of the SEC. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation have been included.

Operating results for the three and six months ended June 30, 2021, are not necessarily indicative of the results that may be expected for the year ending December 31, 2021. The Condensed Consolidated Balance Sheet as of December 31, 2020, was derived from the Company's audited financial statements as of December 31, 2020, included in the Company's Annual Report on Form 10-K filed with the SEC. These financial statements should be read in conjunction with the Company's Annual Report on Form 10-K for the year ended December 31, 2020, which includes a broader discussion of the Company's business and the risks inherent therein.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in the Condensed Consolidated Financial Statements and accompanying notes. Management evaluates its estimates on an ongoing basis including critical accounting policies. Estimates are based on historical experience and on various other market-specific and other relevant assumptions that the Company believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results could differ from those estimates.

Significant Accounting Policies

The Company's significant accounting policies are detailed in its Annual Report on Form 10-K for the year ended December 31, 2020. There have been no significant changes to the Company's significant accounting policies during the three and six months ended June 30, 2021, from those previously disclosed in its 2020 Annual Report on Form 10-K, except to reflect that the Company applies the graded-vesting attribution method to awards with market conditions that include graded-vesting features. Additionally, the Company uses the Monte Carlo Simulation model to evaluate the derived service period and fair value of awards with market conditions, including assumptions of historical volatility and risk-free interest rate commensurate with the vesting term.

Recently Issued Accounting Pronouncements

In June 2016, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, 2016-13, "*Financial Instruments – Credit Losses: Measurement of Credit Losses on Financial Instruments*," or ASU 2016-13. ASU 2016-13 replaces the incurred loss impairment model in current GAAP with a model that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to determine credit loss estimates. ASU 2016-13 is effective for the Company beginning January 1, 2023, with early adoption allowed beginning January 1, 2020. In May 2019, the FASB issued ASU 2019-05, "*Financial Instruments – Credit Losses*," or ASU 2019-05, to allow entities to irrevocably elect the fair value option for certain financial assets previously measured at amortized cost upon adoption of the new credit losses standard. The new effective dates and transition align with those of ASU 2016-13. Management is currently assessing the date of adoption and the impact ASU 2016-13 and ASU 2019-05 will have on the Company, but it does not anticipate adoption of these new standards to have a material impact on the Company's financial position, results of operations or cash flows.

In March 2020, the FASB issued ASU 2020-04, "*Reference Rate Reform (Topic 848): Facilitation of the Effects of Reference Rate Reform on Financial Reporting*." The amendments provide optional guidance for a limited time to ease the potential burden in accounting for reference rate reform. The new guidance provides optional expedients and exceptions for applying U.S. GAAP to contracts, hedging relationships and other transactions affected by reference rate reform if certain criteria are met. The amendments apply only to contracts and hedging relationships that reference LIBOR or another reference rate expected to be discontinued due to reference rate reform. These amendments are effective immediately and may be applied prospectively to contract modifications made and hedging relationships entered into or evaluated on or before December 31, 2022. The Company is currently evaluating its contracts and the optional expedients provided by the new standard, but it does not anticipate its adoption to have a material impact on the Company's financial position, results of operations or cash flows.

2. Investments and Fair Value Measurement

Investments

The Company classifies its marketable securities as available-for-sale and records its investments at fair value. Available-for-sale securities are carried at estimated fair value based on quoted market prices or observable market inputs of almost identical assets, with the unrealized holding gains and losses included in accumulated other comprehensive income (loss). Marketable securities which have maturities beyond one year as of the end of the reporting period are classified as non-current.

The table below summarizes the Company's cash, cash equivalents and short-term investments (in thousands):

	As of June 30, 2021			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and cash equivalents:				
Cash	$ 1,114	$ —	$ —	$ 1,114
Money market funds	25,213	—	—	25,213
Total cash and cash equivalents	26,327	—	—	26,327
Short-term investments:				
Commercial paper	24,436	—	—	24,436
Corporate debt securities	4,562	—	—	4,562
Total short-term investments	28,998	—	—	28,998
Total cash, cash equivalents and short-term investments	$ 55,325	$ —	$ —	$ 55,325

	As of December 31, 2020			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and cash equivalents:				
Cash	$ 5,181	$ —	$ —	$ 5,181
Money market funds	3,996	—	—	3,996
Commercial paper	18,097	—	—	18,097
Total cash and cash equivalents	27,274	—	—	27,274
Short-term investments:				
U.S. government agency securities	5,818	—	—	5,818
Commercial paper	9,794	—	—	9,794
Total short-term investments	15,612	—	—	15,612
Total cash, cash equivalents and short-term investments	$ 42,886	$ —	$ —	$ 42,886

There were no other-than-temporary impairments for these securities at June 30, 2021 or December 31, 2020. No gross realized gains or losses were recognized on the available-for-sale securities and, accordingly, there were no amounts reclassified out of accumulated other comprehensive income (loss) to earnings during the three and six months ended June 30, 2021 and 2020.

As of June 30, 2021, and December 31, 2020, the contractual maturity of all investments held was less than one year.

Fair Value Measurement

The Company's financial instruments consist of Level I and II assets and Level III liabilities. Money market funds are highly liquid investments and are actively traded. The pricing information on these investment instruments are readily available and can be independently validated as of the measurement date. This approach results in the classification of these securities as Level 1 of the fair value hierarchy. For Level II instruments, the Company estimates fair value by utilizing third party pricing services in developing fair value measurements where fair value is based on valuation methodologies such as models using observable market inputs, including benchmark yields, reported trades, broker/dealer quotes, bids, offers and other reference data. Such Level II instruments typically include U.S. treasury, U.S. government agency securities, corporate debt securities and commercial paper. As of June 30, 2021, and December 31, 2020, the Company held, in addition to Level II assets, a contingent put option liability associated with the Loan Agreement with Oxford. See Note 5 "Long-Term Debt" for further description. The Company's estimate of fair value of the contingent put option liability was determined using a risk-neutral valuation model, wherein the fair value of the underlying debt facility is estimated both with and without the presence of the default provisions, holding all other assumptions constant. The resulting difference between the two estimated fair values is the estimated fair value of the default provisions, or the contingent put option, which is included under other long-term liabilities on the Condensed Consolidated Balance Sheets. Changes to the estimated fair value of this liability is recorded in interest income and other income (expense), net in the Condensed Consolidated Statements of Comprehensive Loss. The fair value of the underlying debt facility is estimated by calculating the expected cash flows in consideration of an estimated probability of default and expected recovery rate in default and discounting such cash flows back to the reporting date using a risk-free rate.

The following table sets forth the fair value of the Company's financial assets and liabilities by level within the fair value hierarchy (in thousands):

	As of June 30, 2021			
	Fair Value	Level I	Level II	Level III
Assets				
Money market funds	$ 25,213	$ 25,213	$ —	$ —
Commercial paper	24,436	—	24,436	—
Corporate debt securities	4,562	—	4,562	—
Total assets measured at fair value	$ 54,211	$ 25,213	$ 28,998	$ —
Liabilities				
Contingent put option liability	$ 128	$ —	$ —	$ 128
Total liabilities measured at fair value	$ 128	$ —	$ —	$ 128

	As of December 31, 2020			
	Fair Value	Level I	Level II	Level III
Assets				
Money market funds	$ 3,996	$ 3,996	$ —	$ —
U.S. government agency securities	5,818	—	5,818	—
Commercial paper	27,891	—	27,891	—
Total assets measured at fair value	$ 37,705	$ 3,996	$ 33,709	$ —
Liabilities				
Contingent put option liability	$ 246	$ —	$ —	$ 246
Total liabilities measured at fair value	$ 246	$ —	$ —	$ 246

The following tables set forth a summary of the changes in the fair value of the Company's Level III financial liabilities for the three and six months ended June 30, 2021 and 2020 (in thousands):

	Three Months Ended June 30, 2021	Six Months Ended June 30, 2021
Fair value—beginning of period	$ 181	$ 246
Change in fair value of contingent put option associated with the Loan Agreement	(53)	(118)
Fair value—end of period	$ 128	$ 128

	Three Months Ended June 30, 2020	Six Months Ended June 30, 2020
Fair value—beginning of period	$ 746	$ 437
Change in fair value of contingent put option associated with the Loan Agreement	(155)	154
Fair value—end of period	$ 591	$ 591

3. Inventories, net

Inventories consist of raw materials, work in process and finished goods and are stated at the lower of cost or net realizable value and consist of the following (in thousands):

	Balance as of	
	June 30, 2021	December 31, 2020
Raw materials	$ 277	$ 257
Work-in-process	—	30
Finished goods	1,086	1,339
Total	$ 1,363	$ 1,626

The Company recorded inventory impairment charges of $0 and $0.1 million for the three and six months ended June 30, 2021, respectively, primarily related to Zalviso component parts inventory. For the three and six months ended June 30, 2020, the Company recorded inventory impairment charges of $0.3 million and $0.4 million, respectively. In the six months ended June 30, 2020, $0.3 million of these charges related to the termination of the Grünenthal Agreements, while $0.1 million related to DSUVIA inventory that may expire before being sold.

4. Revenue from Contracts with Customers

The following table summarizes revenue from contracts with customers for the three and six months ended June 30, 2021 and 2020 into categories that depict how the nature, amount, timing and uncertainty of revenue and cash flows are affected by economic factors (in thousands):

	Three months ended June 30, 2021	Six months ended June 30, 2021
Product sales:		
DSUVIA	$ 392	$ 573
Zalviso	—	270
Total product sales	392	843
Contract and collaboration revenue:		
Non-cash royalty revenue related to Royalty Monetization (Note 7)	38	83
Royalty revenue	13	28
Total revenues from contract and other collaboration	51	111
Total revenue	$ 443	$ 954

	Three months ended June 30, 2020	Six months ended June 30, 2020
Product sales:		
DSUVIA	$ 2	$ 157
Zalviso	301	420
Total product sales	303	577
Contract and collaboration revenue:		
Non-cash royalty revenue related to Royalty Monetization (Note 7)	37	121
Royalty revenue	12	40
Other revenue	2,572	2,572
Total revenues from contract and other collaboration	2,621	2,733
Total revenue	$ 2,924	$ 3,310

For additional details on the Company's accounting policy regarding revenue recognition, refer to Note 1 "Organization and Summary of Significant Accounting Policies - Revenue from Contracts with Customers" in the Company's Annual Report on Form 10-K for the year ended December 31, 2020.

Product Sales

The Company's commercial launch of DSUVIA in the United States occurred in the first quarter of 2019. Zalviso was sold in Europe by the Company's collaboration partner, Grünenthal, through May 12, 2021.

Contract and Other Collaboration

Contract and other collaboration revenue includes revenue under the Grünenthal Agreements related to research and development services, non-cash royalty revenue related to the Royalty Monetization and royalty revenue for sales of Zalviso in Europe.

Contract Liability

The following table presents changes in the Company's contract liability for the six months ended June 30, 2021 (in thousands):

	Balance at Beginning of the Period	Additions	Deductions	Balance at the end of the Period
Contract liability:				
Deferred revenue – Grünenthal Agreements	$ 49	$ —	$ (49)	$ —
Deferred revenue	$ 49	$ —	$ (49)	$ —

For the three and six months ended June 30, 2021 and 2020, the Company recognized the following revenue from performance obligations satisfied or eliminated under the Grünenthal Agreements (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Amounts included in contract liabilities at the beginning of the period:				
Performance obligations satisfied	$ —	$ 154	$ 49	$ 233
Performance obligations eliminated upon termination	—	2,572	—	2,572
New activities in the period from performance obligations satisfied:				
Performance obligations satisfied	—	147	221	187
Total revenue from performance obligations satisfied or eliminated	$ —	$ 2,873	$ 270	$ 2,992

5. Long-Term Debt

Loan Agreement with Oxford

On May 30, 2019, the Company entered into the Loan Agreement with Oxford Finance LLC, or Oxford, as the Lender. Under the Loan Agreement, the Lender made a term loan to the Company in an aggregate principal amount of $25.0 million, or the Loan, which was funded on May 30, 2019.

In connection with the Loan Agreement, on May 30, 2019, the Company issued warrants to the Lender and its affiliates, or the Warrants, which are exercisable for an aggregate of 176,679 shares of the Company's common stock with a per share exercise price of $2.83. The Warrants have been classified within stockholders' deficit and accounted for as a discount to the loan by allocating the gross proceeds on a relative fair value basis.

As of June 30, 2021, the accrued balance due under the Loan Agreement with Oxford was $17.2 million. Interest expense related to the Loan Agreement was $0.6 million, $0.2 million of which represented amortization of the debt discount, and $1.2 million, $0.4 million of which represented amortization of the debt discount for the three and six months ended June 30, 2021, respectively, and was $0.9 million, $0.3 million of which represented amortization of the debt discount, and $1.7 million, $0.5 million of which represented amortization of the debt discount, for the three and six months ended June 30, 2020, respectively.

Non-Interest Bearing Payments for the Construction of Leasehold Improvements

In August 2019, the Company entered into a Site Readiness Agreement, or SRA, with Catalent Pharma Solutions, LLC, or Catalent, in contemplation of entering into a commercial supply agreement for its product DSUVIA at a future date. Under the SRA, the Company is building out a suite within Catalent's production facility in Kansas City. If additional equipment and facility modifications are required to meet the Company's product needs, the Company may be required to contribute to the cost of such additional equipment and facility modifications. The Company has determined that it is the owner of the leasehold improvements related to the build-out which will be paid for in four installments of $0.5 million through July 2022. As of June 30, 2021, the accrued balance under the SRA is $0.9 million, and $1.7 million of these leasehold improvements have been capitalized. The effective interest rate at June 30, 2021 was 14.35%. The leasehold improvements are recorded as property and equipment, net, in our Condensed Consolidated Balance Sheets.

6. Leases

Office Leases

The Company leased office and laboratory space for its corporate headquarters, located at 301 – 351 Galveston Drive, Redwood City, California, and had entered into an agreement to sublease approximately 47% of this office and laboratory space.

On March 26, 2021, the Company entered into a Lease Termination Agreement with its landlord and a Sublease Termination Agreement with its sublessee, to terminate the lease and sublease agreements at its corporate headquarters. The termination of both the lease and sublease was effective on April 30, 2021. As of the date of the Lease Termination Agreement, the Company remeasured its lease liability and recorded a gain of $0.5 million upon derecognition of the lease liability and right of use asset for the master lease, which was included in operating expenses for the six months ended June 30, 2021. In connection with the Sublease Termination, the remaining deferred costs of $0.3 million were fully amortized through April 30, 2021, the effective date of the Sublease Termination, and included in operating expenses for the six months ended June 30, 2021.

On March 26, 2021, the Company entered into a Sublease Agreement to sublet space for its corporate headquarters, located at 25821 Industrial Boulevard, Hayward, California. The Sublease Agreement commencement date is April 1, 2021. The Sublease Agreement is for a period of two years and three months with monthly rental payments of $17,000, including one month of abated rent. On the lease commencement date, the Company recognized an operating lease right-of-use asset in the amount of $0.4 million.

Contract Manufacturing Leases

On April 21, 2021, the Company entered into a Commercial Supply Agreement, or the CSA, with Catalent Pharma Solutions, LLC, or Catalent, effective March 31, 2021, under which Catalent will provide certain services to the Company in connection with the processing and packaging of a packaged single dose applicator containing the sublingual tablet 30 mcg sufentanil dosage form contained in the pharmaceutical product, DSUVIA (sufentanil), intended for commercialization.

The term of the CSA is for a period of five years from the first date upon which the FDA approves Catalent as a manufacturer of DSUVIA in the United States, or the Commencement Date. The term shall automatically be extended for successive two-year periods, unless and until one party gives the other party at least 24 months' prior written notice of its desire to terminate as of the end of the then-current term.

The Company will pay Catalent an annual fee of $1.0 million beginning January 1, 2022. Pursuant to the CSA, the Company will purchase each 10-pack carton of DSUVIA from Catalent at an agreed price through December 31, 2022, and pay other fees set forth in the CSA. All pricing and fees, with the exception of raw materials, may be adjusted on an annual basis, effective on January 1 of each calendar year, beginning with January 1, 2023, subject to certain limitations. Price increases for raw materials will be passed through to the Company.

The Company has determined that the fixed fees in the CSA are in-substance lease payments. The Company concluded that this agreement contains an embedded lease as the clean rooms have been built specifically for production of the Company's product and their use is effectively controlled by the Company as it has sole use over the space during the term of the agreement. The Company accounts for the agreement as an operating lease and has evaluated the non-cancelable lease term to be through the binding commitment date of May 15, 2027.

In addition, the Company has entered into an agreement for commercial supply manufacturing services related to the Company's Zalviso drug product with a contract manufacturing organization, which it accounts for as an operating lease.

The components of lease expense are presented in the following table (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Operating lease costs	$ 440	$ 269	$ 780	$ 609
Gain on derecognition of operating lease	—	—	(522)	—
Sublease income	(50)	(149)	(199)	(299)
Loss on termination of sublease	331	—	331	—
Net lease costs	$ 721	$ 120	$ 390	$ 310

The weighted average remaining lease term and discount rate related to the operating leases are presented in the following table:

	June 30, 2021
Weighted-average remaining term – operating lease (in years)	5.41
Weighted-average discount rate – operating lease	12.80%

Future minimum lease payments as of June 30, 2021 are presented in the following table (in thousands):

Year:	
2021 (remaining nine months)	$ 407
2022	1,483
2023	1,144
2024	1,040
2025	1,040
Thereafter	1,454
Total future minimum lease payments	6,568
Less imputed interest	(2,453)
Total	$ 4,115
Reported as:	
Operating lease liabilities	$ 4,618
Operating lease liabilities, current portion	(503)
Operating lease liabilities, net of current portion	$ 4,115

7. Liability Related to Sale of Future Royalties

In September 2015, the Company entered into the Royalty Monetization with PDL for which it received gross proceeds of $65.0 million. Under the Royalty Monetization, PDL will receive 75% of the European royalties under the Amended License Agreement with Grünenthal, as well as 80% of the first four commercial milestones worth $35.6 million (or 80% of $44.5 million), up to a capped amount of $195.0 million over the life of the arrangement.

The Company periodically assesses the expected royalty and milestone payments using a combination of historical results, internal projections and forecasts from external sources. To the extent such payments are greater or less than the Company's initial estimates or the timing of such payments is materially different than its original estimates, the Company will prospectively adjust the amortization of the liability and the effective interest rate. During the three months ended June 30, 2020, Grünenthal notified the Company that it was terminating the Amended License Agreement, effective November 13, 2020. The terms of the Grünenthal Agreements were extended to May 12, 2021 to enable Grünenthal to sell down its Zalviso inventory. The rights to market and sell Zalviso in the Zalviso Territory reverted back to the Company on May 12, 2021. There is a continuing obligation on the Company's part, through the term of the Royalty Monetization with SWK (assignee of PDL), to use commercially reasonable efforts to negotiate a replacement license agreement, or New Arrangement. If the Company is unable to find a New Arrangement, a contingent gain of up to approximately $65 million may be recognized when it is realized upon expiration of the liability at the end of the Royalty Monetization term. Due to the significant judgments and factors related to the estimates of future payments under the Royalty Monetization, there are significant uncertainties surrounding the amount and timing of future payments and the probability of realization of the estimated contingent gain.

The effective interest rate over the life of the liability will be 0% as we record interest income over the remaining term of the arrangement as an offset to the interest expense that was recognized in prior periods. The effective interest income rate for each of the three and six months ended June 30, 2021 and 2020, was approximately 3.6%.

The following table shows the activity within the liability account for the six months ended and the period from inception to June 30, 2021 (in thousands):

	Six months ended June 30, 2021	Period from inception to June 30, 2021
Liability related to sale of future royalties — beginning balance	$ 88,471	$ —
Proceeds from sale of future royalties	—	61,184
Non-cash royalty revenue	(120)	(1,058)
Non-cash interest (income) expense recognized	(1,581)	26,644
Liability related to sale of future royalties as of June 30, 2021	86,770	86,770
Less: current portion	—	—
Liability related to sale of future royalties — net of current portion	$ 86,770	$ 86,770

As royalties are remitted to SWK from ARPI LLC, as described in Note 1 “Organization and Summary of Significant Accounting Policies - Non-Cash Interest Income (Expense) on Liability Related to Sale of Future Royalties” in the Company’s Annual Report on Form 10-K for the year ended December 31, 2020, the balance of the liability will be effectively repaid over the life of the agreement. The Company will record non-cash royalty revenues and non-cash interest expense within its Condensed Consolidated Statements of Comprehensive Loss over the term of the Royalty Monetization.

8. Legal Proceedings

On June 8, 2021, a securities class action complaint was filed in the U.S. District Court for the Northern District of California against the Company and two of its officers. The plaintiff is a purported stockholder of the Company. The complaint alleges that defendants violated Sections 10(b) and 20(a) of the Exchange Act and SEC Rule 10b-5 by making false and misleading statements and omissions of material fact about the Company’s disclosure controls and procedures with respect to its marketing of DSUVIA. The complaint seeks unspecified damages, interest, attorneys’ fees, and other costs. Motions for appointment of lead plaintiff under the Private Securities Litigation Reform Act were filed on August 9, 2021 and a hearing on the motions has been noticed for December 16, 2021.

On July 6, 2021, a purported shareholder derivative complaint was filed in the U.S. District Court for the Northern District of California. The complaint names as defendants ten of the Company’s officers and directors and asserts state and federal claims based on the same alleged misstatements as the shareholder class action complaint. The complaint seeks unspecified damages, attorneys’ fees, and other costs.

The Company believes that these lawsuits are without merit, and intends to vigorously defend against them. Given the uncertainty of litigation, the preliminary stage of the cases, and the legal standards that must be met for, among other things, class certification and success on the merits, the Company cannot estimate the reasonably possible loss or range of loss that may result from these actions.

9. Stockholders’ Equity

Common Stock

Underwritten Public Offering

On January 22, 2021, the Company completed an underwritten public offering in which the Company issued and sold 14,500,000 shares of our common stock to the underwriter at a price of $1.7625 per share. On January 27, 2021, the underwriters exercised their option in full and purchased an additional 2,175,000 shares at a price of $1.7625 per share. The total net proceeds from this offering of an aggregate 16,675,000 shares were approximately $28.9 million.

ATM Agreement

The Company has entered into a Controlled Equity Offering℠ Sales Agreement, or the ATM Agreement, with Cantor Fitzgerald & Co., or Cantor, as agent, pursuant to which the Company may offer and sell, from time to time through Cantor, shares of the Company’s common stock having an aggregate offering price of up to $80.0 million.

During the three and six months ended June 30, 2021, the Company issued and sold approximately 3.0 million shares of common stock pursuant to the ATM Agreement, and received net proceeds of approximately $7.5 million, after deducting fees and expenses. During the three and six months ended June 30, 2020, the Company issued and sold 445,000 and 876,800 shares of common stock pursuant to the ATM Agreement, respectively, for which the Company received net proceeds of approximately $0.7 million and $1.5 million, respectively. As of June 30, 2021, the Company may offer and sell shares of the Company's common stock having an aggregate offering price of up to $36.1 million under the ATM Agreement.

Amended Stock Plan

Amended 2020 Plan

On June 17, 2021, at the 2021 Annual Meeting of Stockholders of the Company, upon the recommendation of the Company's Board of Directors, the Company's stockholders approved an amendment to the Company's 2020 Equity Incentive Plan, or 2020 Plan, or as amended, the Amended 2020 Plan, to increase the number of authorized shares reserved for issuance thereunder by 4,300,000 shares, subject to adjustment for certain changes in the Company's capitalization. The aggregate number of shares of the Company's common stock that may be issued under the Amended 2020 Plan will not exceed the sum of: (i) 4,300,000 shares approved in connection with the adoption of the Amended 2020 Plan, (ii) 5,500,000 shares approved in connection with the original adoption of the 2020 Plan, and (iii) certain shares subject to outstanding awards granted under the 2011 Equity Incentive Plan that may become available for issuance under the 2020 Plan and Amended 2020 Plan, as such shares become available from time to time.

10. Stock-Based Compensation

The Company recorded total stock-based compensation expense for stock options, stock awards and awards made under the Amended 2011 ESPP as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	**2020**	**2021**	**2020**
Cost of goods sold	$ 21	$ 27	$ 43	$ 73
Research and development	200	184	381	384
Selling, general and administrative	951	879	1,837	1,779
Total	$ 1,172	$ 1,090	$ 2,261	$ 2,236

As of June 30, 2021, there were, in the aggregate, 7,589,292 shares available for grant, 14,790,044 options outstanding and 1,834,228 restricted stock units outstanding under the Company's equity incentive plans.

11. Net Loss per Share of Common Stock

The Company's basic net loss per share of common stock is calculated by dividing the net loss by the weighted average number of shares of common stock outstanding for the period. The diluted net loss per share of common stock is computed by giving effect to all potential common stock equivalents outstanding for the period determined using the treasury stock method. For purposes of this calculation, options to purchase common stock, RSUs, and warrants to purchase common stock were considered to be common stock equivalents. In periods with a reported net loss, common stock equivalents are excluded from the calculation of diluted net loss per share of common stock as their effect is antidilutive.

The following outstanding shares of common stock equivalents were excluded from the computation of diluted net loss per share of common stock for the periods presented because including them would have been antidilutive:

	June 30,	
	2021	**2020**
ESPP, RSUs and stock options to purchase common stock	16,907,412	14,816,721
Common stock warrants	176,679	176,679

12. Subsequent Events

Out-License Agreement (DZUVEO)

On July 14, 2021, the Company entered into a License and Commercialization Agreement, or the DZUVEO Agreement, with Aguettant, pursuant to which Aguettant obtained the exclusive right to develop and commercialize DZUVEO in the European Union, Norway, Iceland, Liechtenstein, Andorra, Vatican City, Monaco, Switzerland and the United Kingdom, or the DZUVEO Territory, for the management of acute moderate to severe pain in adults in medically monitored settings. The Company will supply Aguettant with primary packaged product and Aguettant will then complete secondary packaging of the finished product.

The DZUVEO Agreement has an initial term of ten (10) marketing years, with the first marketing year ending on December 31 of the calendar year after the launch of DZUVEO (or December 31, 2022, if the launch occurs between January 1, 2022 and April 30, 2022). The term will automatically renew for successive five marketing year periods unless a party notifies the other party of its intention not to renew at least six (6) months prior to the expiration of the then-current term.

The Company is entitled to receive up to €47.0 million in a combination of up-front and sales-based milestone payments. Aguettant will purchase product from the Company at an agreed price, or the DZUVEO Purchase Price, subject to adjustment. Aguettant will also make revenue share payments that, combined with the DZUVEO Purchase Price, range from 35% to 45% of net sales in the DZUVEO Territory.

Beginning in the third marketing year, the parties will establish binding annual minimums for purchase orders to be submitted by Aguettant. Aguettant has the right to grant sublicenses to its affiliates or, with the prior approval of the Company, third parties, subject to certain limitations.

The DZUVEO Agreement also provides Aguettant with a right of first negotiation for eighteen (18) months before the Company can enter into a collaboration regarding Zalviso in Europe.

In-License Agreement

On July 14, 2021, the Company entered into a License and Commercialization Agreement, or the PFS Agreement, with Aguettant pursuant to which the Company obtained the exclusive right to develop and, subject to FDA approval, commercialize in the United States (i) an ephedrine pre-filled syringe containing 10 ml of a solution of 3 mg/ml ephedrine hydrochloride for injection, and (ii) a phenylephrine prefilled syringe containing 10 ml of a solution of 50 mcg/ml phenylephrine hydrochloride for injection. Aguettant will supply the Company with the products for use in commercialization, if they are approved in the U.S.

The PFS Agreement has an initial term of ten (10) marketing years, with the first marketing year ending on December 31 of the calendar year after the first launch of a product (or December 31 of the same calendar year if the first launch of a product occurs between January 1 and April 30 of a calendar year). The term will automatically renew for successive five marketing year periods unless a party notifies the other party of its intention not to renew at least six (6) months prior to the expiration of the then-current term.

Aguettant is entitled to receive up to $24.0 million in sales-based milestone payments. The Company will purchase each product from Aguettant at an agreed price, or the PFS Purchase Price, subject to adjustment. The Company will also make revenue share payments that, combined with the PFS Purchase Price, will range from 40% to 45% of net sales in the United States.

The Company and Aguettant will agree on minimum sales obligations twelve (12) months prior to the launch of each product.
The Company has the right to grant sublicenses to its affiliates or, with the prior approval of Aguettant, third parties, subject to certain limitations.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis should be read in conjunction with the unaudited financial statements and notes thereto included in Part I, Item 1 of this Quarterly Report on Form 10-Q, or Form 10-Q, and with the audited Consolidated Financial Statements and related notes thereto included as part of our Annual Report on Form 10-K for the year ended December 31, 2020, or Annual Report.

About AcelRx Pharmaceuticals, Inc.

We are a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for use in medically supervised settings.

Our Portfolio

The following table summarizes our portfolio of products and product candidates.

Product/Product Candidate	Description	Target Use	Status
DSUVIA®	Sufentanil sublingual tablet, 30 mcg	Moderate-to-severe acute pain in a medically supervised setting, administered by a healthcare professional	Received U.S. Food and Drug Administration, or FDA, approval in November 2018; commercial launch began first quarter of 2019.
DZUVEO®	Sufentanil sublingual tablet, 30 mcg	Moderate-to-severe acute pain in a medically monitored setting, administered by a healthcare professional	Granted European Commission, or EC, marketing approval in June 2018. Sunset date extended to December 31, 2022 by EC. To be commercialized in Europe by Laboratoire Aguettant.
Zalviso®	Sufentanil sublingual tablet system, 15 mcg	Moderate-to-severe acute pain in the hospital setting, administered by the patient as needed	In the U.S., positive results from Phase 3 trial, IAP312, announced in August 2017. Currently evaluating the timing of the resubmission of the New Drug Application, or NDA, which is in part dependent on the finalization of the FDA's new opioid approval guidelines and process. Approved in the European Union, where it was marketed commercially by Grünenthal through May 12, 2021. We intend to find a replacement license agreement for Zalviso in Europe.
Ephedrine	Ephedrine pre-filled syringe, containing 10 ml of a solution of 3 mg/ml ephedrine hydrochloride for injection	Clinically important hypotension occurring in the setting of anesthesia	Product candidate licensed from Laboratoire Aguettant, or Aguettant, pending submission for approval to FDA under New Drug Application, or NDA. Approved in the European Union, marketed by Aguettant.
Phenylephrine	Phenylephrine prefilled syringe containing 10 ml of a solution of 50 mcg/ml phenylephrine hydrochloride for injection	Clinically important hypotension resulting primarily from vasodilation in the setting of anesthesia.	Product candidate licensed from Aguettant, pending submission for approval to FDA under New Drug Application, or NDA. Approved in the European Union, marketed by Aguettant.
ARX-02	Higher Strength Sufentanil Sublingual Tablet	Cancer breakthrough pain in opioid-tolerant patients	Phase 2 clinical trial and End of Phase 2 meeting completed. Investigational New Drug, or IND, application was inactivated. Future development contingent upon identification of corporate partnership resources.
ARX-03	Combination Sufentanil/Triazolam Sublingual Tablet	Mild sedation and pain relief during painful procedures in a physician's office	Phase 2 clinical trial and End of Phase 2 meeting completed. IND application was inactivated. Future development contingent upon identification of corporate partnership resources.

Out-License Agreement (DZUVEO)

On July 14, 2021, we entered into a License and Commercialization Agreement, or the DZUVEO Agreement, with Aguettant pursuant to which Aguettant obtained the exclusive right to develop and commercialize DZUVEO in the European Union, Norway, Iceland, Liechtenstein, Andorra, Vatican City, Monaco, Switzerland and the United Kingdom, or the DZUVEO Territory, for the management of acute moderate to severe pain in adults in medically monitored settings. We will supply Aguettant with primary packaged product and Aguettant will then complete secondary packaging of the finished product. We are entitled to receive up to €47.0 million in a combination of up-front and sales-based milestone payments. Refer to Note 12 “Subsequent Events” in the accompanying notes to the Condensed Consolidated Financial Statements for additional information.

In-License Agreement

On July 14, 2021, we entered into a License and Commercialization Agreement, or the PFS Agreement, with Aguettant pursuant to which we obtained the exclusive right to develop and, subject to FDA approval, commercialize in the United States (i) an ephedrine pre-filled syringe containing 10 ml of a solution of 3 mg/ml ephedrine hydrochloride for injection, and (ii) a phenylephrine prefilled syringe containing 10 ml of a solution of 50 mcg/ml phenylephrine hydrochloride for injection. Aguettant will supply the Company with the products for use in commercialization, if they are approved in the U.S. Aguettant is entitled to receive up to $24 million in sales-based milestone payments. Refer to Note 12 “Subsequent Events” in the accompanying notes to the Condensed Consolidated Financial Statements for additional information.

General Trends and Outlook

COVID-19-related

Government-mandated orders and related safety policies on account of the COVID-19 pandemic continue to prevent us from operating our business in the normal course. Beginning in early 2020, state and local officials issued orders in response to the pandemic which included, among other things, requirements for residents to shelter in place and for non-essential businesses to cease activities at facilities within certain cities, counties, and states. State and local officials have taken different approaches to these orders, and some have not issued any such orders. Once issued, the orders have been relaxed and then tightened, depending on the rate of COVID-19 cases. As a result of these orders, we implemented a work from home policy for our California-based employees and we continue to adhere to the various and diverse orders issued by government officials in the jurisdictions in which we operate. In addition, some hospitals, ambulatory surgery centers and other healthcare facilities have barred visitors that are not caregivers or mission-critical and otherwise restricted access to such facilities. As a result, the educational and promotional efforts of our commercial and medical affairs personnel have been substantially reduced, and in some cases, stopped. Cancellation or delays of formulary committee meetings and delays of elective surgeries have also affected the pace of formulary approvals and, consequently, the rate of adoption and use of DSUVIA. We expect our near-term sales volumes to continue to be adversely impacted as long as access to healthcare facilities by our commercial and medical affairs personnel continues to be limited, especially in light of the rise in COVID-19 cases associated with the Delta variant. We will continue to evaluate the impact on our revenues and related metrics and operating expenses during this period and assess the need to adjust our expenses and expectations.

As a result of international travel restrictions, the timing for testing and acceptance of our DSUVIA fully automated packaging line, and subsequent FDA approval, has been delayed. Based on our best estimate, now that the line has been installed, we expect FDA approval in 2022.

We will continue to engage with various elements of our supply chain and distribution channel, including our customers, contract manufacturers, and logistics and transportation providers, to meet demand for products and to remain informed of any challenges within our supply chain. We continue to monitor demand and intend to adapt our plans as needed to continue to drive our business and meet our obligations during the evolving COVID-19 pandemic. However, if the COVID-19 pandemic continues and persists for an extended period of time, we may face disruptions to our supply chain and operations, and associated delays in the manufacturing and supply of our products. Such supply disruptions may adversely impact our ability to generate sales of and revenues from our products and our business, financial condition, results of operations and growth prospects could be adversely affected.

As the global pandemic of COVID-19 continues to rapidly evolve, it could result in a significant long-term disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. The extent to which the COVID-19 pandemic impacts our business, our ability to generate sales of and revenues from our approved products, and our future clinical development and regulatory efforts will depend on future developments that are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the outbreak, travel restrictions, quarantines and social distancing requirements in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the virus.

Financial Overview

We have incurred net losses and generated negative cash flows from operations since inception and expect to incur losses in the future as we continue commercialization activities to support the U.S. launch of DSUVIA, support European sales of DZUVEO by Aguettant, and of Zalviso by any replacement partner, and fund any future research and development activities needed to support the FDA regulatory review of our product candidates. As a result, we expect to continue to incur operating losses and negative cash flows until such time as DSUVIA has gained market acceptance and generated significant revenues.

We will incur capital expenditures related to our fully automated packaging line for DSUVIA, which has now been installed, and for which we expect FDA approval in 2022. We anticipate that the fully automated line for DSUVIA will contribute to a significant decrease in costs of goods sold in 2022 and beyond.

Our net loss for the three and six months ended June 30, 2021 was $9.9 million and $18.8 million, respectively, compared to net losses of $6.6 million and $22.5 million for the three and six months ended June 30, 2020, respectively. As of June 30, 2021, we had an accumulated deficit of $457.3 million. As of June 30, 2021, we had cash, cash equivalents and short-term investments totaling $55.3 million compared to $42.9 million as of December 31, 2020.

Critical Accounting Estimates

The accompanying discussion and analysis of our financial condition and results of operations are based upon our unaudited Condensed Consolidated Financial Statements and the related disclosures, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts in our financial statements and accompanying notes. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. To the extent that there are material differences between these estimates and actual results, our future financial statement presentation, financial condition, results of operations and cash flows will be affected. Our critical accounting policies and estimates are detailed in our Annual Report.

There have been no significant changes to our critical accounting policies or significant judgements and estimates for the three and six months ended June 30, 2021, from those previously disclosed in our Annual Report, except to reflect that we apply the graded-vesting attribution method to awards with market conditions that include graded-vesting features. Additionally, we use the Monte Carlo Simulation model to evaluate the derived service period and fair value of awards with market conditions, including assumptions of historical volatility and risk-free interest rate commensurate with the vesting term.

Results of Operations

Our results of operations have fluctuated from period to period and may continue to fluctuate in the future, based upon the progress of our commercial launch of DSUVIA, our research and development efforts, variations in the level of expenditures related to commercial launch, development efforts and debt service obligations during any given period, and the uncertainty as to the extent and magnitude of the impact from the COVID-19 pandemic. Results of operations for any period may be unrelated to results of operations for any other period. In addition, historical results should not be viewed as indicative of future operating results. In particular, to the extent our commercial and medical affairs personnel continue to be subject to varying levels of restriction on accessing hospitals and ambulatory surgical centers due to COVID-19, and to the extent government authorities and certain healthcare providers are continuing to limit elective surgeries, we expect our sales volume to be adversely affected.

Three and Six Months Ended June 30, 2021 and 2020

Revenue

Product Sales Revenue

Product sales revenue consists of sales of DSUVIA in the U.S. and Zalviso in Europe.

Product sales revenue by product for the three and six months ended June 30, 2021 and 2020, was as follows:

	Three Months Ended June 30,				Six Months Ended June 30,			
	2021	2020	$ Change 2021 vs. 2020	% Change 2021 vs. 2020	2021	2020	$ Change 2021 vs. 2020	% Change 2021 vs. 2020
	(In thousands, except percentages)							
DSUVIA	$ 392	$ 2	$ 390	19,500%	$ 573	$ 157	$ 416	265%
Zalviso	—	301	(301)	(100)%	270	420	(150)	(36)%
Total product sales revenue	$ 392	$ 303	$ 89	29%	$ 843	$ 577	$ 266	46%

The increase in product sales revenue for the three and six months ended June 30, 2021, as compared to the three and six months ended June 30, 2020, was primarily the result of increased sales of DSUVIA. Zalviso was sold by Grünenthal GmbH, or Grünenthal, under the Collaboration and License Agreement and the Manufacture and Supply Agreement, or the Grünenthal Agreements in the European Union through May 12, 2021.

Contract and Other Collaboration Revenue

Contract and other collaboration revenue included revenue under the Grünenthal Agreements related to research and development services, non-cash royalty revenue related to the sale of the majority of our royalty rights and certain commercial sales milestones under the Grünenthal Agreements to SWK Funding, LLC, or SWK, (assignee of PDL BioPharma, Inc., or PDL), in a transaction referred to as the Royalty Monetization, and royalty revenue for sales of Zalviso in Europe.

Contract and other collaboration revenue for the three and six months ended June 30, 2021 and 2020, was as follows (in thousands):

	Three Months Ended June 30,				Six Months Ended June 30,			
	2021	2020	$ Change 2021 vs. 2020	% Change 2021 vs. 2020	2021	2020	$ Change 2021 vs. 2020	% Change 2021 vs. 2020
	(In thousands, except percentages)							
Non-cash royalty revenue related to Royalty Monetization (See Note 7)	$ 38	$ 37	$ 1	3%	$ 83	$ 121	$ (38)	(31)%
Royalty revenue	13	12	1	8%	28	40	(12)	(30)%
Other revenue	—	2,572	(2,572)	(100)%	—	2,572	(2,572)	(100)%
Total contract and other collaboration revenue	$ 51	$ 2,621	$ (2,570)	(98)%	$ 111	$ 2,733	$ (2,622)	(96)%

We estimate and recognize royalty revenue and non-cash royalty revenue on a quarterly basis. Adjustments to estimated revenue are recognized in the subsequent quarter based on actual revenue earned per the royalty reports received from Grünenthal. As mentioned above, Grünenthal has terminated the Grünenthal Agreements, accordingly the rights to market and sell Zalviso in Europe reverted back to us on May 12, 2021. In May 2020, upon notification of early termination by Grünenthal, we recognized approximately $2.6 million of deferred revenue for the discount on Zalviso manufacturing services which were no longer a performance obligation.

Cost of Goods Sold

We commenced commercial sales of DSUVIA in the first quarter of 2019.

Total cost of goods sold for the three and six months ended June 30, 2021 and 2020, was as follows (in thousands):

	Three Months Ended June 30,				Six Months Ended June 30,			
	2021	2020	$ Change 2021 vs. 2020	% Change 2021 vs. 2020	2021	2020	$ Change 2021 vs. 2020	% Change 2021 vs. 2020
	(In thousands, except percentages)							
Direct costs	$ 124	$ 379	$ (255)	(67)%	$ 435	$ 625	$ (190)	(30)%
Indirect costs	916	991	(75)	(8)%	1,645	2,256	(611)	(27)%
Total costs of goods sold	$ 1,040	$ 1,370	$ (330)	(24)%	$ 2,080	$ 2,881	$ (801)	(28)%

Direct costs from contract manufacturers for DSUVIA and Zalviso totaled $0.1 million and $0.4 million, respectively, in the three and six months ended June 30, 2021, and included inventory impairment charges of $0 and $0.1 million, respectively, primarily related to Zalviso component parts inventory. Direct costs from contract manufacturers for DSUVIA and Zalviso in the three and six months ended June 30, 2020 totaled $0.4 million and $0.6 million, respectively, and included inventory impairment charges of $0.3 million, and $0.4 million, respectively. In the six months ended June 30, 2020, $0.3 million of these charges related to the termination of the Grünenthal Agreements, while $0.1 million related to DSUVIA inventory that may expire before being sold. Direct cost of goods sold for DSUVIA and Zalviso includes the inventory costs of the active pharmaceutical ingredient, or API, third-party contract manufacturing costs, estimated warranty costs, packaging and distribution costs, shipping, handling and storage costs.

The indirect costs to manufacture DSUVIA and Zalviso totaled $0.9 million and $1.6 million in the three and six months ended June 30, 2021, respectively, while the indirect costs to manufacture DSUVIA and Zalviso totaled $1.0 million and $2.3 million in the three and six months ended June 30, 2020, respectively. Indirect costs include internal personnel and related costs for purchasing, supply chain, quality assurance, depreciation and related expenses.

Research and Development Expenses

The majority of our operating expenses to date have been for research and development activities related to Zalviso and DSUVIA. Research and development expenses included the following:

- expenses incurred under agreements with contract research organizations and clinical trial sites;
- employee-related expenses, which include salaries, benefits and stock-based compensation;
- payments to third party pharmaceutical and engineering development contractors;
- payments to third party manufacturers;
- depreciation and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities and equipment, and equipment and laboratory and other supply costs; and
- costs for equipment and laboratory and other supplies.

We expect to incur future research and development expenditures to support the FDA regulatory review of our product candidates. The timing of the resubmission of the Zalviso NDA is in part dependent on the finalization of the FDA's new opioid approval guidelines and process.

We track external development expenses on a program-by-program basis. Our development resources are shared among all our programs. Compensation and benefits, facilities, depreciation, stock-based compensation, and development support services are not allocated specifically to projects and are considered research and development overhead.

Below is a summary of our research and development expenses for the three and six months ended June 30, 2021 and 2020 (in thousands, except percentages):

	Three Months Ended June 30,				Six Months Ended June 30,			
Drug Indication/Description	**2021**	**2020**	**$ Change 2021 vs. 2020**	**% Change 2021 vs. 2020**	**2021**	**2020**	**$ Change 2021 vs. 2020**	**% Change 2021 vs. 2020**
			(In thousands, except percentages)					
DSUVIA	$ 182	$ 187	$ (5)	(3)%	$ 344	$ 479	$ (135)	(28)%
Zalviso	6	3	3	100%	12	32	(20)	(63)%
Overhead	536	623	(87)	(14)%	1,337	1,714	(377)	(22)%
Total research and development expenses	$ 724	$ 813	$ (89)	(11)%	$ 1,693	$ 2,225	$ (532)	(24)%

Research and development expenses for the three and six months ended June 30, 2021 decreased as compared to the three and six months ended June 30, 2020, primarily due to decreases in personnel-related overhead expenses and DSUVIA-related spending.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consisted primarily of salaries, benefits and stock-based compensation for personnel engaged in commercialization, administration, finance and business development activities. Other significant expenses included allocated facility costs and professional fees for general legal, audit and consulting services.

Total selling, general and administrative expenses for the three and six months ended June 30, 2021 and 2020, were as follows (in thousands, except percentages):

	Three Months Ended June 30,				Six Months Ended June 30,			
	2021	**2020**	**$ Change 2021 vs. 2020**	**% Change 2021 vs. 2020**	**2021**	**2020**	**$ Change 2021 vs. 2020**	**% Change 2021 vs. 2020**
			(In thousands, except percentages)					
Selling, general and administrative expenses	$ 8,694	$ 7,575	$ 1,119	15%	$ 16,338	$ 20,886	$ (4,548)	(22)%

Selling, general and administrative expenses increased by $1.1 million and decreased by $4.5 million during the three and six months ended June 30, 2021, as compared to the three and six months ended June 30, 2020, respectively. The increase for the three months ended June 30, 2021, as compared to the three months ended June 30, 2020 is primarily due to a $0.5 million increase in business development expenses and a $0.5 million increase in facilities-related expenses primarily due to the loss on lease termination of our Redwood City lease. The decrease for the six months ended June 30, 2021, as compared to the six months ended June 30, 2020, is primarily due to net decreases in selling, general and administrative expenses including a $2.0 million reduction in personnel-related costs, a decrease in business development expenses of $1.3 million (primarily due to the termination fee of approximately $1.8 million received in June 2020 from Tetraphase Pharmaceuticals, Inc. related to the termination of our merger agreement), a $0.8 million reduction in DSUVIA commercialization-related expenses, such as travel, and net decreases in other selling, general and administrative expenses of $0.4 million.

In March 2020, we eliminated 30 positions, mainly within the commercial organization. For additional information regarding the Restructuring Costs see Note 1 “Organization and Summary of Significant Accounting Policies” in the Company’s Annual Report on Form 10-K for the year ended December 31, 2020.

Other Income (Expense)

Total other income (expense) for the three and six months ended June 30, 2021 and 2020, was as follows (in thousands, except percentages):

	Three Months Ended June 30,				Six Months Ended June 30,			
	2021	2020	$ Change 2021 vs. 2020	% Change 2021 vs. 2020	2021	2020	$ Change 2021 vs. 2020	% Change 2021 vs. 2020
	(In thousands, except percentages)							
Interest expense	$ (614)	$ (872)	$ 258	(30)%	$ (1,286)	$ (1,727)	$ 441	(26)%
Interest income and other income (expense), net	(16)	270	(286)	(106)%	60	205	(145)	(71)%
Non-cash interest income (expense) on liability related to sale of future royalties	799	834	(35)	(4)%	1,581	1,677	(96)	(6)%
Total other income (expense)	$ 169	$ 232	$ (63)	(27)%	$ 355	$ 155	$ 200	129%

Interest expense consisted primarily of interest accrued or paid on our debt obligation agreements and amortization of debt discounts. Interest expense decreased for the three and six months ended June 30, 2021, as compared to the three and six months ended June 30, 2020, primarily as a result of a lower outstanding loan balance. As of June 30, 2021, the accrued balance due under the Loan Agreement with Oxford was $17.2 million. Refer to Note 5 “Long-Term Debt” in the accompanying notes to the Condensed Consolidated Financial Statements for additional information.

Interest income and other income (expense), net, for the three and six months ended June 30, 2021 and 2020, primarily consisted of interest earned on our investments and the change in the fair value of our contingent put option. Interest income decreased in the three and six months ended June 30, 2021 as compared to the three and six months ended June 30, 2020, primarily due to lower yields on our investments.

The non-cash interest income on the liability related to the sale of future royalties is attributable to the Royalty Monetization that we completed in September 2015. As described in Note 7 “Liability Related to Sale of Future Royalties”, the Royalty Monetization has been recorded as debt under the applicable accounting guidance. We periodically assess the expected royalty and milestone payments using a combination of historical results, internal projections and forecasts from external sources. To the extent such payments are greater or less than our initial estimates or the timing of such payments is materially different than our original estimates, we will prospectively adjust the amortization of the liability and the interest rate.

The effective interest income rate for each of the three and six months ended June 30, 2021 and 2020, was approximately 3.6%. We anticipate that we will record approximately $3 million in non-cash interest income related to the Royalty Monetization for the year ending December 31, 2021.

Liquidity and Capital Resources

Liquidity

We have incurred losses and generated negative cash flows from operations since inception. We expect to continue to incur significant losses in 2021 and may incur significant losses and negative cash flows from operations in the future. We have funded our operations primarily through issuance of equity securities, borrowings, payments from Grünenthal, the monetization of certain future royalties and commercial sales milestones from the European sales of Zalviso by Grünenthal, funding of approximately $22.6 million from the DoD, and more recently with revenues from sales of DSUVIA since the commercial launch in the first quarter of 2019.

As of June 30, 2021, we had cash, cash equivalents and investments totaling $55.3 million compared to $42.9 million as of December 31, 2020. The increase was primarily due to net proceeds received from the issuance of common stock in connection with equity offerings in the first quarter of 2021, partially offset by cash required to fund our continuing operations, including debt service, as we continued our commercialization activities for DSUVIA, including installation of our fully automated packaging line for DSUVIA, and business development activities. We anticipate that our existing capital resources will permit us to meet our capital and operational requirements for at least the next twelve months; however, our expectations may change depending on a number of factors including the extent and magnitude of the impact from the COVID-19 pandemic, in particular the negative impact on sales volumes as our sales force is limited in its access to potential customers, our expenditures related to the United States commercial launch of DSUVIA and the timing of business development activities. Our existing capital resources will not be sufficient to fund our operations until such time as we may be able to generate sufficient revenues to sustain our operations.

On January 22, 2021, we completed an underwritten public offering in which we issued and sold 14,500,000 shares of our common stock to the underwriter at a price of $1.7625 per share. On January 27, 2021, the underwriters exercised their option in full and purchased an additional 2,175,000 shares at a price of $1.7625 per share. The total net proceeds from this offering of an aggregate 16,675,000 shares were approximately $28.9 million.

We entered into a Controlled Equity Offering℠ Sales Agreement, or the ATM Agreement, with Cantor Fitzgerald & Co., or Cantor, as agent, pursuant to which we may offer and sell, from time to time through Cantor, shares of our common stock. As of June 30, 2021, we had issued and sold an aggregate of approximately 14.2 million shares of common stock pursuant to the ATM Agreement, for which we had received net proceeds of approximately $42.6 million, after deducting commissions, fees and expenses of approximately $1.2 million. As of June 30, 2021, we have the ability to sell approximately $36.1 million of our common stock under the ATM Agreement.

On May 30, 2019, we entered into the Loan Agreement with Oxford. Under the Loan Agreement, we borrowed an aggregate principal amount of $25.0 million under a term loan. After deducting all loan initiation costs and outstanding interest on the prior loan agreement with Hercules, we received $15.9 million in net proceeds. As of June 30, 2021, the accrued balance under the Loan Agreement was $17.2 million. For more information, see Note 5 “Long-Term Debt” in the accompanying notes to the Condensed Consolidated Financial Statements.

Our cash and investment balances are held in a variety of interest-bearing instruments, including obligations of commercial paper, corporate debt securities, U.S. government sponsored enterprise debt securities and money market funds. Cash in excess of immediate requirements is invested with a view toward capital preservation and liquidity. We do not expect COVID-19 to have a material impact on our high quality, short-dated investments.

Cash Flows

The following is a summary of our cash flows for the periods indicated and has been derived from our Condensed Consolidated Financial Statements which are included elsewhere in this Form 10-Q (in thousands):

	Six Months Ended June 30,	
	2021	**2020**
Net cash used in operating activities	$ (18,055)	$ (24,054)
Net cash (used in) provided by investing activities	(15,032)	29,578
Net cash provided by financing activities	32,140	1,581

Cash Flows from Operating Activities

The primary use of cash for our operating activities during these periods was to fund commercial activities for our approved product, DSUVIA. Our cash used in operating activities also reflected changes in our working capital, net of adjustments for non-cash charges, such as depreciation and amortization of our fixed assets, stock-based compensation, non-cash interest income (expense) related to the sale of future royalties and interest expense related to our debt financings.

Cash used in operating activities of $18.1 million during the six months ended June 30, 2021, reflected a net loss of $18.8 million, partially offset by aggregate non-cash charges of $2.0 million and included an approximate $1.3 million net change in our operating assets and liabilities. Non-cash charges included $2.3 million for stock-based compensation expense, $1.6 million in non-cash interest income on the liability related to the Royalty Monetization, and $1.0 million in depreciation and amortization expense. The net change in our operating assets and liabilities included a $1.0 million decrease in accrued liabilities.

Cash used in operating activities of $24.1 million during the six months ended June 30, 2020, reflected a net loss of $22.5 million, partially offset by aggregate non-cash charges of $2.3 million and included an approximate $3.8 million net change in our operating assets and liabilities. Non-cash charges included $2.2 million for stock-based compensation expense, $1.7 million in non-cash interest income on the liability related to the royalty monetization and $1.0 million in depreciation expense. The net change in our operating assets and liabilities included a $1.8 million decrease in accrued liabilities, a $2.9 million decrease in deferred revenue and a $0.7 million increase in accounts payable.

Cash Flows from Investing Activities

Our investing activities have consisted primarily of our capital expenditures and purchases and sales and maturities of our available-for-sale investments.

During the six months ended June 30, 2021, cash used in investing activities of $15.0 million was primarily the net result of $38.2 million for purchases of investments and $1.6 million for purchases of property and equipment, partially offset by $24.8 million in proceeds from maturity of investments. During the six months ended June 30, 2020, cash provided by investing activities of $29.6 million was the net result of $58.6 million in proceeds from maturity of investments, offset by $28.8 million for purchases of investments and purchases of property and equipment of $0.2 million.

Cash Flows from Financing Activities

Cash flows from financing activities primarily reflect proceeds from the sale of our securities and payments made on debt financings.

During the six months ended June 30, 2021, cash provided by financing activities of $32.1 million was primarily due to $36.4 million in net proceeds received in connection with equity financings, partially offset by $4.2 million used for payment of long-term debt. During the six months ended June 30, 2020, cash provided by financing activities was primarily due to $1.4 million in net proceeds received under the ATM Agreement and $0.2 million in proceeds as a result of stock purchases made under our Amended 2011 ESPP, partially offset by $0.1 million used for payment of employee tax obligations relating to the vesting of restricted stock units.

Operating Capital and Capital Expenditure Requirements

Our current operating plan includes expenditures related to the continued launch of DSUVIA in the United States. This plan includes an assumption that COVID-19 related restrictions will not increase considerably, and includes anticipated activities required to resubmit the Zalviso NDA. These assumptions may change as a result of many factors. We will continue to evaluate the work necessary to successfully launch DSUVIA and gain approval of our product candidates in the United States and intend to update our cash forecasts accordingly. Our forecast that our existing capital resources will permit us to meet our capital and operational requirements through at least the next twelve months is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially.

Our future capital requirements may vary materially from our expectations based on numerous factors, including, but not limited to, the following:

- the impact and timing of COVID-19 on our operations, our sales representatives' access to hospitals or other healthcare facilities, and our level of sales;
- expenditures related to the launch of DSUVIA and potential commercialization of our product candidates, if approved;
- future manufacturing, selling and marketing costs related to DSUVIA and our product candidates, if approved, including our contractual obligations to Aguettant under the DZUVEO Agreement;
- costs associated with business development activities and licensing transactions;
- the outcome, timing and cost of the regulatory submissions for our product candidates and any approvals for our product candidates;
- the initiation, progress, timing and completion of any post-approval clinical trials for DSUVIA, or our product candidates, if approved;
- changes in the focus and direction of our business strategy and/or research and development programs;
- milestone and royalty revenue we receive under our collaborative development and commercialization arrangements, including the DZUVEO Agreement;
- delays that may be caused by changing regulatory requirements;
- the costs involved in filing and prosecuting patent applications and enforcing and defending patent claims;
- the timing and terms of future in-licensing and out-licensing transactions;
- the cost and timing of establishing sales, marketing, manufacturing and distribution capabilities;
- the cost of procuring clinical and commercial supplies of DSUVIA and our product candidates, if approved;
- the extent to which we acquire or invest in businesses, products and product candidates or technologies; and
- the expenses associated with litigation.

In the long-term, our existing capital resources will not be sufficient to fund our operations until such time as we may be able to generate sufficient revenues to sustain our operations. We will have to raise additional funds through the sale of our equity securities, monetization of current and future assets, issuance of debt or debt-like securities or from development and licensing arrangements to sustain our operations and continue our development programs.

Please see “Part II., Item 1A. Risk Factors—Risks Related to Our Financial Condition and Need for Additional Capital.”

Off-Balance Sheet Arrangements

Through June 30, 2021, we have not entered into any off-balance sheet arrangements and do not have any holdings in variable interest entities.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and are not required to provide the information specified under this item.

Item 4. Controls and Procedures

We maintain disclosure controls and procedures (as defined in Exchange Act Rule 13a–15(e) and 15d-15(e)) that are designed to ensure that information required to be disclosed in our reports under the Securities Exchange Act of 1934, as amended, or the Exchange Act, and the rules and regulations thereunder, is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Evaluation of disclosure controls and procedures. As required by Rule 13a-15(b) under the Exchange Act, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on the foregoing, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in internal control over financial reporting. There have been no changes in our internal control over financial reporting during our most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

From time to time we may be involved in legal proceedings relating to intellectual property, commercial, employment and other matters arising in the ordinary course of business. Such matters are subject to uncertainty and there can be no assurance that such legal proceedings will not have a material adverse effect on our business, results of operations, financial position or cash flows. Other than the following, we believe there are no legal proceedings pending that could, individually or in the aggregate, have a material adverse effect on our results of operations or financial condition:

On June 8, 2021, a securities class action complaint was filed in the U.S. District Court for the Northern District of California against us and two of our officers. The plaintiff is a purported stockholder of the Company. The complaint alleges that defendants violated Sections 10(b) and 20(a) of the Exchange Act and SEC Rule 10b-5 by making false and misleading statements and omissions of material fact about our disclosure controls and procedures with respect to our marketing of DSUVIA. The complaint seeks unspecified damages, interest, attorneys’ fees, and other costs. Motions for appointment of lead plaintiff under the Private Securities Litigation Reform Act were filed on August 9, 2021 and a hearing on the motions has been noticed for December 16, 2021. Please see “*Item 1A. Risk Factors—Risks of a General Nature -- Our involvement in securities-related class action litigation could divert our resources and management's attention and harm our business.*”

On July 6, 2021, a purported shareholder derivative complaint was filed in the U.S. District Court for the Northern District of California. The complaint names ten of our officers and directors and asserts state and federal claims based on the same alleged misstatements as the shareholder class action complaint. The complaint seeks unspecified damages, attorneys’ fees, and other costs. Please see “*Item 1A. Risk Factors—Risks of a General Nature—Litigation may substantially increase our costs and harm our business.*”

We believe that these lawsuits are without merit, and we intend to vigorously defend against them. Given the uncertainty of litigation, the preliminary stage of the cases, and the legal standards that must be met for, among other things, class certification and success on the merits, we cannot estimate the reasonably possible loss or range of loss that may result from these actions.

Item 1A. Risk Factors

This Quarterly Report on Form 10-Q contains forward-looking information based on our current expectations. Because our actual results may differ materially from any forward-looking statements made by or on behalf of us, this section includes a discussion of important factors that could affect our actual future results, including, but not limited to, our revenues, expenses, net loss and loss per share. You should carefully consider these risk factors, together with all of the other information included in this Quarterly Report on Form 10-Q as well as our other publicly available filings with the U.S. Securities and Exchange Commission, or SEC.

Summary Risk Factors

Our business is subject to numerous risks, as more fully described in this section below this summary. You should read these risks before you invest in our common stock. We may be unable, for many reasons, including those that are beyond our control, to implement our business strategy. In particular, our risks include:

- Our business is being adversely impacted by the COVID-19 pandemic.
- We have incurred significant losses since our inception, anticipate that we will continue to incur significant losses in 2021 and may continue to incur losses in the future.
- We have not yet generated significant product revenue and may never be profitable.
- We will require additional capital and may be unable to raise capital, which would force us to delay, reduce or eliminate our commercialization efforts and product development programs and could cause us to cease operations.
- Positive clinical results obtained to date for Zalviso may be disputed in FDA review, do not guarantee regulatory approval and may not be obtained from future clinical trials.
- Existing and future legislation may increase the difficulty and cost for us to commercialize our products and affect the prices we may obtain.
- Guidelines and recommendations published by government agencies, as well as non-governmental organizations, and existing laws and regulations can reduce the use of DSUVIA, and Zalviso, if approved in the United States.
- Zalviso may cause adverse effects or have other properties that could delay or prevent regulatory approval or limit the scope of any approved label or market acceptance. DSUVIA may cause adverse effects or have other properties that could limit market acceptance.
- Although we have obtained regulatory approval for DSUVIA, and even if we obtain regulatory approval for Zalviso in the United States, we and our collaborators face extensive regulatory requirements and our products may face future development and regulatory difficulties.
- The commercial success of DSUVIA and Zalviso, if approved, in the United States, as well as DZUVEO and Zalviso in Europe, will depend upon the acceptance of these products by the medical community, including physicians, nurses, patients, and pharmacy and therapeutics committees.
- If we are unable to maintain or grow our sales and marketing capabilities or enter into agreements with third parties to market and sell our products, we may be unable to generate sufficient product revenue.
- A key part of our business strategy is to establish collaborative relationships to commercialize and fund development and approval of our products, particularly outside of the United States. We may not succeed in establishing and maintaining collaborative relationships, which may significantly limit our ability to develop and commercialize our products successfully, if at all.
- If we cannot defend our issued patents from third party claims or if our pending patent applications fail to issue, our business could be adversely affected.
- The market price of our common stock may be highly volatile.
- Litigation may substantially increase our costs and harm our business.
- Our involvement in securities-related class action litigation could divert our resources and management's attention and harm our business.

We have marked with an asterisk (*) those risks described below that reflect substantive changes from, or additions to, the risks described in our Annual Report on Form 10-K for the year ended December 31, 2020.

Risks Related to COVID-19 Pandemic

Our business is being adversely impacted by the COVID-19 pandemic.*

Our business has been adversely affected by the COVID-19 outbreak. Federal, state, local and foreign government orders on account of the COVID-19 pandemic are preventing us from conducting certain activities. Following local and state government orders in California, where our corporate office is located and many of our employees live, we implemented work from home policies, which are limiting certain of our operations. If the COVID-19 outbreak continues, we may need to limit operations further and implement additional limitations, such as extending our work from home policies.

In response to the COVID-19 pandemic, some hospitals, ambulatory surgery centers and other healthcare facilities have barred visitors that are not caregivers or mission-critical and we have no visibility as to when these restrictions on access will be lifted for all of our customers. As a result, our commercial and medical affairs teams' educational and promotional efforts have been reduced, and in some cases, stopped. Furthermore, some governments, hospitals and doctors, as a measure to combat the further spread of COVID-19, reduced the number of procedures in which DSUVIA is administered as part of the pain treatment program, and temporarily halted performing elective surgeries, which adversely impacted the level of our sales relating to such procedures. We expect our near-term sales volumes to be adversely impacted for as long as access to healthcare facilities by our commercial and medical affairs personnel and the number of procedures in which DSUVIA is administered continues to be limited. The ultimate impact of the COVID-19 outbreak remains highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, healthcare systems or the global economy as a whole. However, these effects could have a material impact on our operations, and we will continue to monitor the COVID-19 situation closely.

Risks Related to Commercialization

Our success is highly dependent on our ability to successfully commercialize DSUVIA.*

We invested a significant portion of our efforts and financial resources to develop and gain regulatory approval for DSUVIA and expect to continue making significant investments to commercialize DSUVIA. We believe our success is highly dependent on, and a significant portion of the value of our company relates to, our ability to successfully commercialize DSUVIA in the United States. The commercial success of DSUVIA depends heavily on numerous factors, including:

- our ability to market, sell, and distribute DSUVIA;
- our ability to establish and maintain commercial manufacturing with third parties;
- acceptance by the medical community, including physicians, nurses, patients and pharmacy and therapeutics committees;
- acceptance of pricing and placement on payers' formularies;
- our ability to effectively compete with other medications for the treatment of moderate-to-severe acute pain in medically supervised settings, including IV-opioids and any subsequently approved products;
- effective management of, and compliance with, the DSUVIA Risk Evaluation and Mitigation Strategy, or REMS, program;
- continued demonstration of an acceptable safety profile of DSUVIA; and
- our ability to obtain, maintain, enforce, and defend our intellectual property rights and claims.

If we are unable to successfully commercialize DSUVIA, our business, financial condition, and results of operations will be materially harmed.

The commercial success of DSUVIA and, if approved, Zalviso and our other product candidates in the United States, as well as DZUVEO and Zalviso in Europe, will depend upon the acceptance of these products by the medical community, including physicians, nurses, patients, and pharmacy and therapeutics committees.*

The degree of market acceptance of DSUVIA and, if approved, Zalviso and our other product candidates in the United States, as well as DZUVEO and Zalviso in Europe, by the medical community will depend on a number of factors, including:

- demonstration of clinical safety and efficacy compared to other products;
- the relative convenience, ease of administration and acceptance by physicians, patients and health care payers;
- the use of our approved products by a healthcare professional for patient types that were not specifically studied in clinical trials;
- the prevalence and severity of any adverse events, or AEs, or serious adverse events, or SAEs;
- overcoming any perceptions of sufentanil as a potentially unsafe drug due to its high potency opioid status;
- limitations or warnings contained in the U.S. Food and Drug Administration, or FDA, -approved label for DSUVIA and, if approved, our other product candidates, or the European Medicines Agency, or EMA,-approved label for DZUVEO or Zalviso;
- restrictions or limitations placed on DSUVIA due to the REMS program or, if approved, on our product candidates;
- availability of alternative treatments;
- existing capital investment by hospitals in IV PCA technology;
- pricing and cost-effectiveness;

- the effectiveness of our current or any future collaborators' sales and marketing strategies;
- our ability to obtain formulary approvals; and
- our ability to obtain and maintain sufficient third-party coverage and reimbursement.

If our approved products do not achieve an adequate level of acceptance by the medical community, including physicians, nurses, patients and pharmacy and therapeutics committees, we may not generate sufficient revenue and become or remain profitable.

If we are unable to maintain or grow our sales and marketing capabilities or enter into agreements with third parties to market and sell our products, we may be unable to generate sufficient product revenue.*

In order to commercialize DSUVIA and our product candidates, if approved, in the United States, we must maintain or grow internal sales, marketing, distribution, managerial and other capabilities or make arrangements with third parties to perform these services. We have entered into agreements with third parties for the distribution of DSUVIA and may enter into such agreements for our product candidates, if approved, in the United States, including the product candidates we in-licensed from Laboratoire Aguettant, or Aguettant, in July 2021 pursuant to a License and Commercialization Agreement, or the PFS Agreement; however, if these third parties do not perform as expected or there are delays in establishing such relationships, our ability to effectively distribute products would suffer.

We have entered into strategic partnerships with third parties to commercialize our products outside of the United States. For example, in 2013 we entered into a collaboration with Grünenthal GmbH, or Grünenthal, for the commercialization of Zalviso in Europe and Australia, and in July 2021, we entered a License and Commercialization Agreement, or the DZUVEO Agreement, with Aguettant for the commercialization of DZUVEO in the European Union, Norway, Iceland, Liechtenstein, Andorra, Vatican City, Monaco, Switzerland and the United Kingdom, or the DZUVEO Territory. Grünenthal ceased commercializing Zalviso on May 12, 2021 and the rights to market and sell Zalviso reverted back to us. We intend to enter into additional strategic partnerships with third parties to commercialize our products outside of the United States, including a replacement license agreement for Zalviso in Europe. Per the terms of the royalty monetization arrangement with SWK Funding, LLC, or SWK (assignee of PDL BioPharma, Inc., or PDL), or the Royalty Monetization, we are obligated to use commercially reasonable efforts to negotiate a replacement license agreement, or New Arrangement. Accordingly, even if we are able to enter into a New Arrangement, and that licensee is successful in commercializing Zalviso in Europe, we will receive only a portion of any royalties until the capped amount owing to SWK is reached.

We face significant competition in seeking appropriate strategic partners, and these strategic partnerships can be intricate and time consuming to negotiate and document. We may not be able to negotiate future strategic partnerships on acceptable terms, or at all. We are unable to predict when, if ever, we will enter into any new strategic partnerships because of the numerous risks and uncertainties associated with establishing strategic partnerships. Our current or future collaboration partners, if any, may not dedicate sufficient resources to the commercialization of our products and product candidates, if approved, or may otherwise fail in their commercialization due to factors beyond our control. If we are unable to establish effective collaborations to enable the sale of our products to healthcare professionals and in geographical regions that will not be covered by our own marketing and sales force, or if our potential future collaboration partners do not successfully commercialize our products, our ability to generate revenues from product sales will be adversely affected.

If we are unable to maintain or grow adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate sufficient product revenue and become profitable. We compete with many companies that currently have extensive and well-funded marketing and sales operations. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

A key part of our business strategy is to establish collaborative relationships to commercialize and fund development and approval of our products, particularly outside of the United States. We may not succeed in establishing and maintaining collaborative relationships, which may significantly limit our ability to develop and commercialize our products successfully, if at all.*

We will need to establish and maintain successful collaborative relationships to obtain international sales, marketing and distribution capabilities for our products. The process of establishing and maintaining collaborative relationships is difficult, time-consuming and involves significant uncertainty. For example:

- our partners may seek to renegotiate or terminate their relationships with us due to unsatisfactory clinical or regulatory results, manufacturing issues, a change in business strategy, a change of control or other reasons;
- our contracts for collaborative arrangements are or may be terminable at will on written notice and may otherwise expire or terminate, and we may not have alternatives available to achieve the potential for our products in those territories or markets;
- our partners may choose to pursue alternative technologies, including those of our competitors;

- we may have disputes with a partner that could lead to litigation or arbitration, including in connection with any contractual force majeure notices tied to the COVID-19 pandemic;

- we have limited control over the decisions of our partners, and they may change the priority of our programs in a manner that would result in termination of the agreement or add significant delays to the partnered program;

- our ability to generate future payments and royalties from our partners depends upon the abilities of our partners to establish the safety and efficacy of our drugs, maintain regulatory approvals and our ability to successfully manufacture and achieve market acceptance of our products;

- we or our partners may fail to properly initiate, maintain or defend our intellectual property rights, where applicable, or a party may use our proprietary information in such a way as to invite litigation that could jeopardize or potentially invalidate our proprietary information or expose us to potential liability;

- our partners may not devote sufficient capital or resources towards our products; and

- our partners may not comply with applicable government regulatory requirements necessary to successfully market and sell our products.

If any collaborator fails to fulfill its responsibilities in a timely manner, or at all, any research, clinical development, manufacturing or commercialization efforts pursuant to that collaboration could be delayed or terminated, or it may be necessary for us to assume responsibility for expenses or activities that would otherwise have been the responsibility of our collaborator. For example, Grünenthal has terminated the collaboration agreement for the commercialization of Zalviso in Europe. The rights to market and sell Zalviso in Europe reverted back to us on May 12, 2021. We have a continuing obligation, through the term of the Royalty Monetization with SWK, to use commercially reasonable efforts to negotiate a New Arrangement. If we are unable to establish and maintain collaborative relationships on acceptable terms we may have to undertake development and commercialization activities at our own expense.

In March 2020, we reduced the size of our commercial team and, given our reduced workforce, we may experience difficulties in retaining our existing employees and managing our operations, including our continued commercialization of DSUVIA.

In March 2020, we reduced the size of our commercial team to eliminate the overlap with the Tetraphase Pharmaceuticals, Inc. commercial team under our co-promotion arrangement and reduce operating expenses. The restructuring resulted in the elimination of 30 positions, or approximately 33% of our workforce. As of June 30, 2021, we had approximately 25 sales representatives, inclusive of both internal and external resources.

We will need to retain and maintain our existing sales, managerial, operational, finance and other personnel and resources in order to continue the commercialization of DSUVIA and manage our operations. Our current infrastructure may be inadequate to support our strategy and our workforce reduction may be disruptive to our operations, may negatively affect our productivity, and constrain our commercialization activities. For example, our workforce reduction could yield unanticipated consequences, such as attrition beyond planned staff reductions, negative impact on employee morale and our corporate culture, or increase difficulties in our day-to-day operations and prevent us from successfully commercializing DSUVIA as rapidly as planned. If we encounter such unanticipated consequences, we may have difficulty retaining and attracting personnel. In addition, the implementation of any additional workforce or expense reduction programs may divert the efforts of our management team and other key employees, which could adversely affect our business. Furthermore, we may not realize, in full or in part, the anticipated benefits, savings and improvements in our cost structure from our cost reduction plan, due to unforeseen difficulties, delays or unexpected costs. If we are unable to realize the expected operational efficiencies and cost savings from the cost reduction plan, our operating results and financial condition would be adversely affected.

Guidelines and recommendations published by government agencies, as well as non-governmental organizations, and existing laws and regulations can reduce the use of DSUVIA, and Zalviso, if approved in the United States.

Government agencies and non-governmental organizations promulgate regulations and guidelines applicable to certain drug classes that may include DSUVIA and Zalviso, if approved in the United States. Recommendations of government agencies or non-governmental organizations may relate to such matters as maximum quantities dispensed to patients, dosage, route of administration, and use of concomitant therapies. Government agencies and non-governmental organizations have offered commentary and guidelines on the use of opioid-containing products. We are uncertain how these activities and guidelines may impact DSUVIA and our ability to gain marketing approval of Zalviso in the United States. Regulations or guidelines suggesting the reduced use of certain drug classes that may include DSUVIA or Zalviso, or the use of competitive or alternative products as the standard-of-care to be followed by patients and healthcare providers, could result in decreased use of DSUVIA or Zalviso, if approved, or negatively impact our ability to gain market acceptance and market share. The U.S. government and state legislatures have prioritized combatting the growing misuse and addiction to opioids and opioid overdose deaths and have enacted legislation and regulations as well as other measures intended to fight the opioid epidemic. Addressing opioid drug abuse is a priority for the current U.S. administration and the FDA and is part of a broader initiative led by the U.S. Department of Health and Human Services, or HHS. Overall, there is greater scrutiny of entities involved in the manufacture, sale and distribution of opioids. These initiatives, existing laws and regulations, and any negative publicity related to opioids may have a material impact on our business and our ability to manufacture opioid products.

Governmental investigations, inquiries, and regulatory actions and lawsuits brought against us by government agencies and private parties with respect to our commercialization of opioids could adversely affect our business, financial condition, results of operations and cash flows.

As a result of greater public awareness of the public health issue of opioid abuse, there has been increased scrutiny of, and investigation into, the commercial practices of opioid manufacturers by state and federal agencies. As a result of our manufacturing and commercial sale of DSUVIA in the United States and Zalviso in Europe, we could become the subject of federal, state and foreign government investigations and enforcement actions, focused on the misuse and abuse of opioid medications.

In addition, a significant number of lawsuits have been filed against opioid manufacturers, distributors, and others in the supply chain by cities, counties, state Attorney's General and private persons seeking to hold them accountable for opioid misuse and abuse. The lawsuits assert a variety of claims, including, but not limited to, public nuisance, negligence, civil conspiracy, fraud, violations of the Racketeer Influenced and Corrupt Organizations Act, or RICO, or similar state laws, violations of state Controlled Substance Acts or state False Claims Acts, product liability, consumer fraud, unfair or deceptive trade practices, false advertising, insurance fraud, unjust enrichment and other common law and statutory claims arising from defendants' manufacturing, distribution, marketing and promotion of opioids and seek restitution, damages, injunctive and other relief and attorneys' fees and costs. The claims generally are based on alleged misrepresentations and/or omissions in connection with the sale and marketing of prescription opioid medications and/or an alleged failure to take adequate steps to prevent abuse and diversion. While DSUVIA is designed for use solely in certified medically supervised healthcare settings and administered only by a healthcare professional in these settings, and is not distributed or available at retail pharmacies to patients by prescription, we can provide no assurance that parties will not file lawsuits of this type against us in the future. In addition, current public perceptions of the public health issue of opioid abuse may present challenges to favorable resolution of any potential claims. Accordingly, we cannot predict whether we may become subject to these kinds of investigations and lawsuits in the future, and if we were to be named as a defendant in such actions, we cannot predict the ultimate outcome. Any allegations against us may negatively affect our business in various ways, including through harm to our reputation.

If we were required to defend ourselves in these matters, we would likely incur significant legal costs and could in the future be required to pay significant amounts as a result of fines, penalties, settlements or judgments. It is unlikely that our current product liability insurance would fully cover these potential liabilities, if at all. Moreover, we may be unable to maintain insurance in the future on acceptable terms or with adequate coverage against potential liabilities or other losses. For more information about our product liability insurance and exclusions therefrom, please see the risk factor entitled "We face potential product liability claims, and, if such claims are successful, we may incur substantial liability" elsewhere in this section. The resolution of one or more of these matters could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Furthermore, in the current climate, stories regarding prescription drug abuse and the diversion of opioids and other controlled substances are frequently in the media or advocated by public interest groups. Unfavorable publicity regarding the use or misuse of opioid drugs, the limitations of abuse-deterrent formulations, the ability of drug abusers to discover previously unknown ways to abuse opioid products, public inquiries and investigations into prescription drug abuse, litigation, or regulatory activity regarding sales, marketing, distribution or storage of opioids could have a material adverse effect on our reputation and impact on the results of litigation.

Finally, various government entities, including Congress, state legislatures or other policy-making bodies, or public interest groups have in the past and may in the future hold hearings, conduct investigations and/or issue reports calling attention to the opioid crisis, and may mention or criticize the perceived role of manufacturers, including us, in the opioid crisis. Similarly, press organizations have and likely will continue to report on these issues, and such reporting may result in adverse publicity for us, resulting in reputational harm.

Approval of Zalviso and DZUVEO in Europe has resulted in a variety of risks associated with international operations that could materially adversely affect our business.*

Our collaborations with international partners, including Grünenthal and Aguettant, have required, and will require, us to supply product to support the commercialization of our products in Europe and it is likely that any New Arrangement would also include such a requirement. Entering into international business relationships subjects us to additional risks including:

- multiple, conflicting, and changing laws and regulations such as privacy and data regulations, transparency regulations, tax laws, export and import restrictions, employment laws, regulatory requirements, including for drug approvals, and other governmental approvals, permits, and licenses;

- EMA "sunset clause" requirements, which apply to DZUVEO, providing that the marketing authorization of a medicine will cease to be valid if it is not placed on the market within three years of the authorization being granted or if it is removed from the market for three consecutive years; however, the European Commission has extended this date to December 31, 2022 for DZUVEO;

- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- different payer reimbursement regimes, governmental payers, patient self-pay systems and price controls;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from pandemics, geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

Any of these factors could have a material adverse effect on our business.

If we, or current and potential partners, are unable to compete effectively, our products may not reach their commercial potential.

The U.S. biotechnology and pharmaceutical industries are characterized by intense competition and cost pressure. DSUVIA competes, and our product candidates, if approved in the U.S., will compete, with a number of existing and future pharmaceuticals and drug delivery devices developed, manufactured and marketed by others. In particular, DSUVIA may compete with a wide variety of products and product candidates including (i) injectable opioid products, such as morphine, fentanyl, hydromorphone and meperidine; (ii) oral opioids such as oxycodone and hydrocodone; (iii) generic injectable local anesthetics, such as bupivacaine or branded formulations thereof; (iv) non-steroidal anti-inflammatory drugs, or NSAIDS, including ketorolac in intranasal or generic IV form, and IV meloxicam; and (v) transmucosal fentanyl products. Zalviso, if approved in the U.S., may compete with a number of opioid-based treatment options, including IV PCA pumps, oral PCA devices, and transdermal opioid PCAs. The PFS product candidates, if approved in the U.S., may compete with other ready-to-use formulations of ephedrine and phenylephrine.

Key competitive factors affecting the commercial success of our approved products are likely to be efficacy, safety profile, reliability, convenience of dosing, price and reimbursement. Many of our competitors and potential competitors have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of drug candidates, obtaining FDA and other regulatory approval of products, and the commercialization of those products. Accordingly, our competitors may be more successful than we are in obtaining FDA approval for drugs and achieving widespread market acceptance. Our competitors' drugs or drug delivery systems may be more effective, have fewer adverse effects, be less expensive to develop and manufacture, or be more effectively marketed and sold than any product we may seek to commercialize. This may render our products obsolete or non-competitive. We anticipate that we will face intense and increasing competition as new drugs enter the market, additional technologies become available, and competitors establish collaborative or licensing relationships, which may adversely affect our competitive position. These and other competitive risks may materially adversely affect our ability to attain or sustain profitable operations.

Hospital or other health care facility formulary approvals for DSUVIA or our product candidates, if approved, in the United States may not be achieved, or could be subject to certain restrictions, which could make it difficult for us to sell our products.

Obtaining hospital or other health care facility formulary approvals can be an expensive and time-consuming process. We cannot be certain if and when we will obtain formulary approvals to allow us to sell our products into our target markets. In particular, the restrictions on our commercial and medical affairs teams' access to hospitals and other health care facilities has adversely impacted the number of formulary approvals we anticipated achieving in 2020, and for as long as these restrictions remain in place, or new restrictions are implemented, we may have limited visibility or difficulties in obtaining these formulary approvals in the future. Failure to obtain timely formulary approval will limit our commercial success. If we are successful in obtaining formulary approvals, we may need to complete evaluation programs whereby DSUVIA, or our product candidates, if approved, is used on a limited basis for certain patient types. The evaluation period may last several months and there can be no assurance that use during the evaluation period will lead to formulary approvals of DSUVIA, or our product candidates, if approved. Further, even successful formulary approvals may be subject to certain restrictions based on patient type or hospital protocol. Failure to obtain timely formulary approvals for DSUVIA, or our product candidates, if approved, would materially adversely affect our ability to attain or sustain profitable operations.

Coverage and adequate reimbursement may not be available for DSUVIA or our product candidates, if approved, in the United States, or DZUVEO or Zalviso in Europe, which could make it difficult for us, or our partners, to sell our products profitably.

Our ability to commercialize DSUVIA or our product candidates, if approved, in the United States, and any collaboration partner's ability to commercialize DZUVEO or Zalviso in Europe successfully will depend, in part, on the extent to which coverage and adequate reimbursement will be available from government payer programs at the federal and state levels, authorities, including Medicare and Medicaid, private health insurers, managed care plans and other third-party payers.

No uniform policy requirement for coverage and reimbursement for drug products exists among third-party payers in the United States or Europe. Therefore, coverage and reimbursement can differ significantly from payer to payer. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payer separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Our inability to promptly obtain and sufficiently maintain coverage and adequate reimbursement rates from third party payers could significantly harm our operating results, our ability to raise capital needed to commercialize our approved drugs and our overall financial condition.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and other third-party payers have attempted to control costs by limiting coverage and the amount of reimbursement for particular medical products. There have been a number of legislative and regulatory proposals to change the healthcare system in the United States and in some foreign jurisdictions that could affect our ability to sell our products profitably. These legislative and/or regulatory changes may negatively impact the reimbursement for our products, following approval. The availability of numerous generic pain medications may also substantially reduce the likelihood of reimbursement for DSUVIA or Zalviso, if approved, in the United States, and DSUVIA/DZUVEO and Zalviso in Europe and elsewhere. The application of user fees to generic drug products may expedite the approval of additional pain medication generic drugs. We expect to experience pricing pressures in connection with our sales of DSUVIA and Zalviso, if approved, in the United States, and future product sales of Zalviso and DZUVEO in Europe, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. If we fail to successfully secure and maintain reimbursement coverage for our products or are significantly delayed in doing so, we will have difficulty achieving market acceptance of our products and our business will be harmed.

Furthermore, market acceptance and sales of our products will depend on reimbursement policies and may be affected by future healthcare reform measures. Government authorities and third-party payers, such as private health insurers, hospitals and health maintenance organizations, decide which drugs they will pay for and establish reimbursement levels. We cannot be sure that reimbursement will be available for DSUVIA or our product candidates, if approved, in the United States, or DZUVEO or Zalviso in Europe. Also, reimbursement amounts may reduce the demand for, or the price of, our products. For example, we anticipate we may need comparator studies of DZUVEO in Europe to ensure premium reimbursement in certain countries. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize DSUVIA or our product candidates, if approved, in the United States, or DZUVEO or Zalviso in Europe.

Additionally, the regulations that govern marketing approvals, pricing, coverage and reimbursement for new drugs vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a product before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues able to be generated from the sale of the product in that country. For example, separate pricing and reimbursement approvals may impact any future collaboration partners' ability to market and successfully commercialize our products in the 27 member states of the European Union. Adverse pricing limitations may hinder our ability to recoup our investment in DSUVIA in the United States, or Zalviso, even after obtaining FDA marketing approval.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

If we are found to have improperly promoted off-label uses of our products, including DSUVIA or our product candidates, if approved, in the United States, we may become subject to significant liability. Such enforcement has become more common in the industry. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription drug products. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. While we have received marketing approval for DSUVIA for our proposed indication, physicians may nevertheless use our products for their patients in a manner that is inconsistent with the approved label, if the physicians personally believe in their professional medical judgment it could be used in such manner. However, if the FDA determines that our promotional materials or training constitutes promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine or criminal penalties and a requirement for corrective advertising, including Dear Doctor letters. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an off-label use, which could result in significant civil, criminal and/or administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from government-funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, increased losses and diminished profits and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results. The FDA or other enforcement authorities could also request that we enter into a consent decree or a corporate integrity agreement or seek a permanent injunction against us under which specified promotional conduct is monitored, changed or curtailed. If we cannot successfully manage the promotion of DSUVIA or our product candidates, if approved, in the United States, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

If we are unable to establish and maintain relationships with group purchasing organizations any future revenues or future profitability could be jeopardized.

Many end-users of pharmaceutical products have relationships with group purchasing organizations, or GPOs, whereby such GPOs provide such end-users access to a broad range of pharmaceutical products from multiple suppliers at competitive prices and, in certain cases, exercise considerable influence over the drug purchasing decisions of such end-users. Hospitals and other end-users contract with the GPO of their choice for their purchasing needs. We expect to derive revenue from end-user customers that are members of GPOs for DSUVIA and our product candidates, if approved. Establishing and maintaining strong relationships with these GPOs will require us to be a reliable supplier, remain price competitive and comply with FDA regulations. The GPOs with whom we have relationships may have relationships with manufacturers that sell competing products, and such GPOs may earn higher margins from these products or combinations of competing products or may prefer products other than ours for other reasons. If we are unable to establish or maintain our GPO relationships, sales of DSUVIA and our product candidates, if approved, and related revenues could be negatively impacted.

We intend to rely on a limited number of distributors and pharmaceutical wholesalers to distribute DSUVIA and our product candidates, if approved, in the United States.

We intend to rely primarily upon distributors and pharmaceutical wholesalers in connection with the distribution of DSUVIA and our product candidates, if approved, in the United States. As part of the DSUVIA REMS program, we monitor distribution and audit wholesalers' data and will monitor such data from other distributors. If our distributors and wholesalers do not comply with the DSUVIA REMS requirements, or if we are unable to establish or maintain our business relationships with these distributors and pharmaceutical wholesalers on commercially acceptable terms, or if our distributors and wholesalers are unable to distribute our drugs for regulatory, compliance or any other reason, it could have a material adverse effect on our sales and may prevent us from achieving profitability.

Risks Related to Clinical Development and Regulatory Approval

Existing and future legislation may increase the difficulty and cost for us to commercialize our products and affect the prices we may obtain.*

In the United States and some foreign jurisdictions, the legislative landscape continues to evolve, including changes to the regulation of opioid-containing products. There have been a number of legislative and regulatory changes and proposed changes regarding healthcare systems that could prevent or delay marketing approval of Zalviso outside of Europe. These changes will restrict or regulate post-approval activities for DSUVIA, DZUVEO and Zalviso, and affect our ability to profitably sell any products for which we obtain marketing approval. For example, in February 2016, the FDA announced a comprehensive action plan to take concrete steps towards reducing the impact of opioid abuse on American families and communities. As part of this plan, the FDA announced that it intended to review product and labeling decisions and re-examine the risk-benefit paradigm for opioids. In June 2019, the FDA issued draft guidance related to a new benefit/risk framework for new opioid analgesic products, which proposes that the new product candidate show some benefit over an existing product. In September 2019, the FDA held a public hearing to receive stakeholder input on the approval process for new opioids. In January 2020, FDA's Anesthetic and Analgesic Drug Products Advisory Committee recommended against the approval of a new opioid analgesic, oxycodegol, the NDA for which was subsequently withdrawn by its sponsor. The timing of the resubmission of the Zalviso NDA is dependent upon the finalization of the FDA's new opioid approval guidelines and process.

In the European Union, or EU, the pricing of prescription drugs is subject to government control. The EU also provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. In addition, the EMA has a "sunset clause" which provides that the marketing authorization of a medicine will cease to be valid if it is not placed on the market within three years of the authorization being granted or if it is removed from the market for three consecutive years; however, the European Commission has extended this date to December 31, 2022 for DZUVEO.

In the United States, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the Affordable Care Act was enacted in an effort to, among other things, broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, impose new taxes and fees on the health industry and impose additional health policy reforms. Aspects of the Affordable Care Act that may impact our business include:

- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- expansion of eligibility criteria for Medicaid programs, thereby potentially increasing manufacturers' Medicaid rebate liability;
- expansion of healthcare fraud and abuse laws, including the federal False Claims Act and the federal Anti-Kickback Statute, new government investigative powers and enhanced penalties for non-compliance; and
- a Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

The Affordable Care Act continues to substantially change health care financing and delivery by both governmental and private insurers, which may increase our regulatory burdens and operating costs.

There have been executive, judicial and Congressional challenges to certain aspects of the Affordable Care Act. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the Affordable Care Act have been signed into law. The Tax Cuts and Jobs Act of 2017 includes a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the Affordable Care Act will remain in effect in its current form. Moreover, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the Affordable Care Act marketplace, which began on February 15, 2021 and will remain open through August 15, 2021. The executive order instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the Affordable Care Act. . It is possible that the Affordable Care Act will be subject to judicial or Congressional challenges in the future. It is also unclear how any such challenges and the healthcare reform measures of the Biden administration will impact the Affordable Care Act. We expect that the Affordable Care Act and other healthcare reform measures that may be adopted in the future, could have a material adverse effect on our industry generally and on our ability to successfully commercialize our products. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we or our collaborators are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or our collaborators are not able to maintain regulatory compliance, our products may lose regulatory approval and we may not achieve or sustain profitability, which would adversely affect our business.

In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. Aggregate reductions of Medicare payments to providers of 2% per fiscal year went into effect on April 1, 2013 and due to subsequent legislative amendments to the statute will stay in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through December 31, 2021 due to the COVID-19 pandemic, unless Congressional action is taken. The American Taxpayer Relief Act further reduced Medicare payments to several providers, including hospitals.

Moreover, the Drug Supply Chain Security Act of 2013 imposes additional obligations on manufacturers of pharmaceutical products, among others, related to product tracking and tracing. Among the requirements of this legislation, manufacturers are required to provide certain information regarding the drug product to individuals and entities to which product ownership is transferred, label drug product with a product identifier, and keep certain records regarding the drug product.

In the United States, there has been increasing legislative and enforcement interest with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing and reform government program reimbursement methodologies for drugs. At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, President Trump announced several executive orders related to prescription drug pricing that attempt to implement several of the administration's proposals. The FDA also released a final rule, effective November 30, 2020, implementing a portion of the importation executive order providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which has also been delayed until January 1, 2023. Further, on November 20, 2020, CMS issued an interim final rule implementing President Trump's Most Favored Nation, or MFN, executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. On December 28, 2020, the U.S. District Court for the Northern District of California issued a nationwide preliminary injunction against implementation of the interim final rule. On January 13, 2021, in a separate lawsuit brought by industry groups in the U.S. District Court of Maryland, the government defendants entered a joint motion to stay litigation on the condition that the government would not appeal the preliminary injunction granted in the U.S. District Court for the Northern District of California and that performance for any final regulation stemming from the MFN model interim final rule shall not commence earlier than sixty (60) days after publication of that regulation in the Federal Register. Additionally, based on a recent executive order, the Biden administration expressed its intent to pursue certain policy initiatives to reduce drug prices. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, measures designed to encourage importation from other countries and bulk purchasing. Furthermore, even after initial price and reimbursement approvals, reductions in prices and changes in reimbursement levels can be triggered by multiple factors, including reference pricing systems and publication of discounts by third party payers or authorities in other countries. In Europe, prices can be reduced further by parallel distribution and parallel trade, i.e., arbitrage between low-priced and high-priced countries. If any of these events occur, revenue from sales of Zalviso and DZUVEO in Europe would be negatively affected.

Legislative and regulatory proposals have been made to expand post-approval requirements and further restrict sales and promotional activities for pharmaceutical products. We are not sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our products, if any, may be.

We expect that additional healthcare reform measures will be adopted within and outside the United States in the future, any of which could negatively impact our business. For instance, it is possible that additional governmental action is taken in response to the COVID-19 pandemic. The continuing efforts of the government, insurance companies, managed care organizations and other payers of healthcare services to contain or reduce costs of healthcare may adversely affect the demand for any drug products for which we have obtained or may obtain regulatory approval, our ability to set a price that we believe is fair for our products, our ability to obtain coverage and reimbursement approval for a product, our ability to generate revenues and achieve or maintain profitability, and the level of taxes that we are required to pay.

We may experience market resistance, delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory agency policy regarding opioids generally, and sufentanil specifically.

In February 2016, the FDA announced a comprehensive action plan to take concrete steps towards reducing the impact of opioid abuse on American families and communities. As part of this plan, the FDA announced that it intended to review product and labeling decisions and re-examine the risk-benefit paradigm for opioids. In June 2019, the FDA issued draft guidance related to a new benefit/risk framework for new opioid analgesic products, which proposes that the new product candidate show some benefit over an existing product. In September 2019, the FDA held a public hearing to receive stakeholder input on the approval process for new opioids. The timing of the resubmission of the Zalviso NDA is dependent upon the finalization of the FDA's new opioid approval guidelines and process.

In May 2017, an Opioid Policy Steering Committee was established to address and advise regulators on opioid use. The Committee was charged with three initial questions: (i) should the FDA require mandatory education for healthcare professionals, or HCPs, who prescribe opioids; (ii) should the FDA take steps to ensure the number of prescribed opioid doses is more closely tailored to the medical indication; and (iii) is the FDA properly considering the risk of abuse and misuse of opioids during its drug review process. Zalviso has not been designed with an abuse-deterrent formulation and is not tamper-resistant. As a result, Zalviso has not undergone testing for tamper-resistance or abuse deterrence.

The FDA can delay, limit or deny marketing approval for many reasons, including:

- a product candidate may not be considered safe or effective;
- the manufacturing processes or facilities we have selected may not meet the applicable requirements; and
- changes in their approval policies or adoption of new regulations may require additional work on our part.

Part of the regulatory approval process includes compliance inspections of manufacturing facilities to ensure adherence to applicable regulations and guidelines. The regulatory agency may delay, limit or deny marketing approval of our product candidate, Zalviso, as a result of such inspections. We, our contract manufacturers, and their vendors, are all subject to preapproval and post-approval inspections at any time. The results of these inspections could impact our ability to obtain FDA approval for Zalviso and, if approved, our ability to launch and successfully commercialize Zalviso in the United States. In addition, results of FDA inspections could impact our ability to maintain FDA approval of DSUVIA, and our ability to expand and sustain commercial sales of DSUVIA in the United States.

Any delay in, or failure to receive or maintain, approval for Zalviso in the United States could prevent us from generating meaningful revenues or achieving profitability. Zalviso may not be approved even if we believe it has achieved its endpoints in clinical trials. Regulatory agencies, including the FDA, or their advisors, may disagree with our trial design and our interpretations of data from preclinical studies and clinical trials. Regulatory agencies may change requirements for approval even after a clinical trial design has been approved. The FDA exercises significant discretion over the regulation of combination products, including the discretion to require separate marketing applications for the drug and device components in a combination product. Zalviso is being regulated as a drug product under the NDA process administered by the FDA. The FDA could in the future require additional regulation of Zalviso, or DSUVIA, under the medical device provisions of the Federal Food, Drug and Cosmetic Act, or FDCA. We must comply with the Quality Systems Regulation, or QSR, which sets forth the FDA's current good manufacturing practice, or cGMP, requirements for medical devices, and other applicable government regulations and corresponding foreign standards for drug cGMPs. If we fail to comply with these regulations, it could have a material adverse effect on our business and financial condition.

Regulatory agencies also may approve a product candidate for fewer or more limited indications than requested or may grant approval subject to the performance of post-marketing trials. For example, DSUVIA is subject to a deferred post-marketing requirement for study in the pediatric population ages 6-17 years. As required in the DSUVIA FDA approval letter, a final protocol for this trial was submitted to the FDA in August 2020, in conjunction with a request to defer initiation of pediatric studies until additional post-market safety data is obtained in adult patients using DSUVIA. In addition, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates. For example, we intend to seek approval of Zalviso for the management of moderate-to-severe acute pain in adult patients in the hospital setting; however, our clinical trial data was generated exclusively from the post-operative segment of this population, and the FDA may restrict any approval to post-operative patients only, which would reduce the size of the commercial opportunity.

The success of Zalviso relies, in part, on obtaining regulatory approval in the United States.

The success of Zalviso relies, in part, upon our ability to develop and receive regulatory approval of this product candidate in the United States for the management of moderate-to-severe acute pain in adult patients in the hospital setting. Our Phase 3 program for Zalviso initially consisted of three Phase 3 clinical trials. We reported positive top-line data from each of these trials and submitted an NDA for Zalviso to the FDA in September 2013, which the FDA then accepted for filing in December 2013. In July 2014, the FDA issued a Complete Response Letter, or CRL, for our NDA for Zalviso, or the Zalviso CRL. The Zalviso CRL contained requests for additional information on the Zalviso System to ensure proper use of the device. The requests include submission of data demonstrating a reduction in the incidence of device errors, changes to address inadvertent dosing, among other items, and submission of additional data to support the shelf life of the product. Furthermore, in March 2015, we received correspondence from the FDA stating that in addition to the bench testing and two Human Factors studies we had performed in response to the issues identified in the Zalviso CRL, a clinical trial was needed to assess the risk of inadvertent dispensing and overall risk of dispensing failures. Based on the results of our Type C meeting with the FDA in September 2015, we completed the protocol review with the FDA and initiated this study, IAP312, in September 2016.

IAP312 was a Phase 3 study in post-operative patients designed to evaluate the effectiveness of changes made to the functionality and usability of the Zalviso device and to take into account comments from the FDA on the study protocol. The IAP312 study was designed to rule out a 5% device failure rate. The study design required a minimum of 315 patients. In the IAP312 study, sites proactively looked for tablets that were dispensed by the patient but failed to be placed under the tongue, known as dropped tablets. The FDA refers to dropped tablets as inadvertent dispensing. Correspondence from the FDA suggests that they may include the rate of inadvertent dispensing along with the device failures to calculate a total error rate. The IAP312 study evaluated all incidents of misplaced tablets; however, per the protocol, the error rate calculation does not include the rate of inadvertent dispensing. If the FDA includes the rate of inadvertent dispensing along with the device failures to calculate a total error rate, the resulting error rate may be unacceptable to the FDA. Further, the correspondence from the FDA suggests that we may need to modify the REMS program for Zalviso to address dropped tablets. The IAP312 results will supplement the three Phase 3 trials already completed in the Zalviso NDA resubmission. The timing of the resubmission of the Zalviso NDA is dependent upon the finalization of the FDA's new opioid approval guidelines and process.

There is no guarantee that the additional work we performed related to Zalviso, including the IAP312 trial, will result in our successfully obtaining FDA approval of Zalviso in a timely fashion, if at all. Although we believe the IAP312 study met safety, satisfaction and device usability expectations, there is no guarantee the IAP312 trial results will address the issues raised by the FDA. For example, the FDA may include the rate of inadvertent dispensing along with the device failures to calculate a total error rate and the resulting error rate may be unacceptable to the FDA, or the FDA may still have concerns regarding the performance of the device, inadvertent dosing (dropped tablets), or other issues. At any future point in time, the FDA could require us to complete further clinical, Human Factors, pharmaceutical, reprocessing or other studies, which could delay or preclude any NDA resubmission or approval of the NDA and could require us to obtain significant additional funding. We may not be able to identify appropriate remediations to issues that the FDA may raise, and we may not have sufficient time or financial resources to conduct future activities to remediate issues raised by the FDA. We intend to seek a label indication for Zalviso for the management of moderate-to-severe acute pain in adult patients in the hospital setting. However, our clinical trial data was generated exclusively from the post-operative segment of this population, and the FDA may restrict any approval to post-operative patients only, which would reduce our commercial opportunity.

Upon resubmission of the Zalviso NDA, the FDA may hold an advisory committee meeting to obtain committee input on the safety and efficacy of Zalviso. Typically, advisory committees will provide responses to specific questions asked by the FDA, including the committee's view on the approvability of the drug under review. Advisory committee decisions are not binding, but an adverse decision at the advisory committee may have a negative impact on the regulatory review of Zalviso. Additionally, we may choose to engage in the dispute resolution process with the FDA.

Our proposed trade name of Zalviso has been approved by the EMA and is currently being used in Europe. It has also been conditionally approved by the FDA, which must approve all drug trade names to avoid medication errors and misbranding. However, the FDA may withdraw this approval in which case any brand recognition or goodwill that we establish with the name Zalviso prior to commercialization may be worthless.

Any delay in approval by the FDA of the Zalviso NDA, once it is resubmitted, may negatively impact our stock price and harm our business operations. Any delay in obtaining, or inability to obtain, regulatory approval would prevent us from commercializing Zalviso in the United States, generating revenues and potentially achieving profitability. If any of these events occur, we may be forced to delay or abandon our development efforts for Zalviso, which would have a material adverse effect on our business.

Positive clinical results obtained to date for Zalviso may be disputed in FDA review, do not guarantee regulatory approval and may not be obtained from future clinical trials.

We have reported positive top-line data from each of our four Zalviso Phase 3 clinical trials completed to date, as well as our Phase 2 clinical trials for Zalviso. However, even if we believe that the data obtained from clinical trials is positive, the FDA has, and in the future could, determine that the data from our trials was negative or inconclusive or could reach a different conclusion than we did on that same data. Negative or inconclusive results of a clinical trial or difference of opinion could cause the FDA to require us to repeat the trial or conduct additional clinical trials prior to obtaining approval for commercialization, and there is no guarantee that additional trials would achieve positive results or that the FDA will agree with our interpretation of the results. If the FDA were to require any additional clinical trials for Zalviso, our development efforts would be further delayed, which would have a material adverse effect on our business. Any such determination by the FDA would delay the timing of our commercialization plan for Zalviso and adversely affect our business operations.

Delays in clinical trials are common and have many causes, and any delay could result in increased costs to us and jeopardize or delay our ability to obtain regulatory approval and commence product sales.

We have experienced and may in the future experience delays in clinical trials of our product candidates. While we have completed four Phase 3 clinical trials and several Phase 2 clinical trials for Zalviso, future clinical trials may not begin on time, have an effective design, enroll a sufficient number of patients or be completed on schedule, if at all. For example, we postponed the start of IAP312, originally planned for the first quarter of 2016, to September 2016. The postponement was due to a delay in the receipt and testing of final clinical supplies for this trial. As a result, the development timeline for Zalviso was further extended.

Our post-approval clinical trials for DSUVIA, or any future FDA-required clinical trials for Zalviso, could be delayed for a variety of reasons, including:

- inability to raise funding necessary to initiate or continue a trial;
- delays in obtaining regulatory approval to commence a trial;
- delays in reaching agreement with the FDA on final trial design;
- imposition of a clinical hold by the FDA, Institutional Review Board, or IRB, or other regulatory authorities;
- delays in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites;
- delays in obtaining required IRB approval at each site;
- delays in recruiting suitable patients to participate in a trial;
- delays in the testing, validation, manufacture and delivery of the tablets and device components of DSUVIA or Zalviso;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;

- clinical sites dropping out of a trial to the detriment of enrollment or being delayed in entering data to allow for clinical trial database closure;
- time required to add new clinical sites; or
- delays by our contract manufacturers to produce and deliver sufficient supply of clinical trial materials.

If any future FDA-required clinical trials are delayed for any reason, our development costs may increase, our approval process for Zalviso could be delayed, our ability to commercialize and commence sales of Zalviso could be materially harmed, and our ability to maintain FDA approval of DSUVIA could be jeopardized, which could have a material adverse effect on our business.

Zalviso may cause adverse effects or have other properties that could delay or prevent regulatory approval or limit the scope of any approved label or market acceptance. DSUVIA may cause adverse effects or have other properties that could limit market acceptance.

Adverse events, or AEs, caused by Zalviso could cause us, other reviewing entities, clinical trial sites or regulatory authorities to interrupt, delay or halt any future FDA-required clinical trials and could result in the denial of regulatory approval. Phase 2 clinical trials we conducted with Zalviso did generate some AEs, but no significant adverse events, or SAEs, related to the trial drug. In our Phase 3 active-comparator clinical trial (IAP309), 8% of Zalviso-treated patients dropped out of the trial prematurely due to an AE (11% in the IV patient-controlled morphine group), and we observed three serious adverse events, or SAEs, that were assessed as possibly or probably related to study drug (one- respiratory depression in the Zalviso group and two- abdominal distension and ileus in the IV patient-controlled morphine group). In our Phase 3, double-blind, placebo-controlled, abdominal surgery trial (IAP310), 6% of Zalviso-treated patients dropped out of the trial prematurely due to an AE (9% in placebo group). There were no SAEs determined to be related to study drug. In our Phase 3, double-blind, placebo-controlled, orthopedic surgery trial (IAP311), 7% of Zalviso-treated patients dropped out of the trial prematurely due to an AE (7% in placebo group). Four patients (three in the Zalviso group and one in the placebo group) experienced an SAE considered possibly or probably related to the trial drug by the investigator. The SAEs possibly or probably attributed to Zalviso were severe oxygen saturation decrease, sinus tachycardia and confusional state. In our Phase 3 multicenter, open-label study of Zalviso (IAP312), 3% of patients dropped out prematurely due to an AE. Five patients experienced SAEs in the IAP312 study and none of these were considered possibly or probably related to the study drug by the investigator.

In our Phase 2 DSUVIA placebo-controlled bunionectomy study (SAP202), two patients in the DSUVIA 30 mcg group (5%) discontinued treatment due to an AE, one unrelated to study drug and the other probably related to study drug. There were no SAEs deemed related to study drug. In our Phase 3 placebo-controlled abdominal surgery study (SAP301), one DSUVIA-treated patient (1%) dropped out of the trial prematurely due to an AE (4% in placebo group). There were two SAEs determined to be related to study drug in the placebo-treated group and no related SAEs in the DSUVIA group. In our Phase 3 open-label, single-arm emergency room study (SAP302), no DSUVIA-treated patients dropped out of the trial prematurely due to an AE. One patient had an SAE - angina pectoris - possibly related to study drug. In our post-operative study in patients aged 40 years or older (SAP303), 3% of DSUVIA-treated patients dropped out of the trial prematurely due to an AE. There were no SAEs deemed related to study drug.

If DSUVIA or, if approved, Zalviso cause serious or unexpected side effects after receiving marketing approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of the product or impose restrictions on its distribution in the form of a modified REMS program;
- regulatory authorities may require the addition of labeling statements, such as warnings or contraindications;
- we may be required to change the way the product is administered or conduct additional clinical trials;
- we could be sued and held liable for harm caused to patients; or
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of DSUVIA or, if approved, Zalviso, and could substantially increase the costs of commercializing our products.

Additional time may be required to obtain U.S. regulatory approval for Zalviso because it is a drug/device combination product candidate.

DSUVIA and Zalviso are combination products with both drug and device components. The FDA requires both the drug and device components of combination product candidates to be reviewed as part of an NDA submission. There are very few examples of the FDA approval process for drug/device combination products such as DSUVIA and Zalviso. As a result, we experienced delays in the development and commercialization of DSUVIA, and may experience future delays in the development and commercialization of Zalviso, due to regulatory uncertainties in the product development and approval process, in particular as it relates to a drug/device combination product approval under an NDA.

The process for obtaining approval of an NDA is time consuming, subject to unanticipated delays and costs, and requires the commitment of substantial resources.

If the FDA determines that any of the clinical work submitted, including the clinical trials, Human Factors studies and bench testing submitted for a product candidate in support of an NDA were not conducted in full compliance with the applicable protocols for these trials, studies and testing as well as with applicable regulations and standards, or if the FDA does not agree with our interpretation of the results of such trials, studies and testing, the FDA may reject the data and results. The FDA may audit some or all of our clinical trial sites to determine the integrity of our clinical data. The FDA may audit some or all of our Human Factors study sites to determine the integrity of our data and may audit the data and results of bench testing. Any rejection of any of our data would negatively impact our ability to obtain marketing authorization for our product candidate, Zalviso, and would have a material adverse effect on our business and financial condition. In addition, an NDA may not be approved, or approval may be delayed, as a result of changes in FDA policies for drug approval during the review period. For example, although many products have been approved by the FDA in recent years under Section 505(b)(2) of the FDCA, objections have been raised to the FDA's interpretation of Section 505(b)(2). If challenges to the FDA's interpretation of Section 505(b) (2) are successful, the FDA may be required to change its interpretation, which could delay or prevent the approval of such an NDA. More generally, the FDA's comprehensive action plan to take concrete steps towards reducing the impact of opioid abuse on American families and communities may result in delays and challenges in obtaining NDA approval. Any significant delay in the acceptance, review or approval of an NDA that we have submitted would have a material adverse effect on our business and financial condition and would require us to obtain significant additional funding.

Although we have obtained regulatory approval for DSUVIA, and even if we obtain regulatory approval for Zalviso in the United States, we and our collaborators face extensive regulatory requirements, and our products may face future development and regulatory difficulties.*

Although we have obtained regulatory approval for DSUVIA, and even if we obtain regulatory approval for Zalviso in the United States, the FDA may impose significant restrictions on the indicated uses or marketing of our products or impose ongoing requirements for potentially costly post-approval trials or post-market surveillance. For example, DSUVIA is subject to a deferred post-marketing requirement for study in the pediatric population ages 6-17 years. A final protocol for this trial was submitted to the FDA in August 2020, in conjunction with a request to defer initiation of pediatric studies until additional post-market safety data is obtained in adult patients using DSUVIA. Additionally, the labeling approved for DSUVIA includes restrictions on use due to the opioid nature of sufentanil. If approved, the labeling for Zalviso will likely include similar restrictions on use.

DSUVIA in the United States is also subject to ongoing FDA requirements governing the labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, record-keeping and reporting of safety and other post-market information. The holder of an approved NDA is obligated to monitor and report AEs and any failure of a product to meet the specifications in the NDA. The holder of an approved NDA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process.

Advertising and promotional materials must comply with FDA rules concerning the advertising and promotion of DSUVIA and are subject to FDA review, in addition to other potentially applicable federal and state laws. Failure to comply with these regulations can result in the receipt of warning letters and further liability if off-label promotion is involved. For example, on February 11, 2021, we received a warning letter from the Office of Prescription Drug Promotion, or OPDP, of the FDA relating to a banner advertisement we submitted to the OPDP on December 6, 2019, and a tabletop display we submitted on February 28, 2020, and resubmitted to the OPDP at its request on September 23, 2020. We submitted the materials to the OPDP pursuant to the FDA requirement that sponsors submit all promotional materials to the FDA at the time of their initial dissemination or publication. The FDA's concerns identified in the letter include its view that the promotional material makes misleading claims and representations about the risks and efficacy of DSUVIA because the material does not reveal facts that are material in light of the representations made. As a result, we conducted a review of our marketing materials to identify any potential revisions in light of the letter. We responded to the FDA within the timeframe requested in the letter and, on March 23, 2021, held a teleconference with OPDP to seek guidance and clarification on the concerns raised in the letter. Following our meeting with OPDP, we conducted a further review of our marketing materials to identify any potential revisions in light of the letter and OPDP's guidance. We submitted a second response to FDA on April 7, 2021 and on June 17, 2021, we announced that the FDA agreed with our proposed plan to update certain promotional materials, including providing a letter to healthcare professionals, or the DHCP letter, explaining the corrections to the discontinued promotional materials. We will also include this DHCP letter on the DSUVIA.com website for a period of eight months. Although we believe we have updated all promotional materials currently in use by our commercial team to address the FDA's concerns and we expect to receive a close-out letter from the FDA after the DHCP letters have been sent to the identified healthcare professionals and the letter has been posted on the website for eight months, we cannot give any assurances that we will receive such close-out letter or that we will not receive additional FDA warning letters in the future. If approved, Zalviso will be subject to these same requirements.

We must also register and obtain various state prescription drug distribution licenses and controlled substance permits, and any delay or failure to obtain or maintain these licenses or permits may limit our market and materially impact our business. In certain states we cannot apply for a license until a drug is approved by the FDA. The state licensing process may take several months which would delay commercialization in those states. In addition, manufacturers of drug products and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMPs and adherence to commitments made in the NDA. If we, or a regulatory agency, discover previously unknown problems with a product, such as AEs of unanticipated severity or frequency, or problems with the facilities where the product is manufactured, a regulatory agency may impose restrictions relative to that product or the manufacturing facilities, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

If we fail to comply with applicable regulatory requirements following approval of our products, a regulatory agency may:

- issue a warning letter asserting that we are in violation of the law;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve a pending NDA or supplements to an NDA submitted by us;
- seize product; or
- refuse to allow us to enter into supply contracts, including government contracts.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize DSUVIA, or, if approved, Zalviso, and generate revenues.

Except for Zalviso and DZUVEO, which are both approved in Europe, we may never obtain additional regulatory approvals for our products and product candidates outside of the United States, which would limit our ability to realize their full market potential.*

In order to market any products outside of the United States, we or our commercial partners, must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. On September 22, 2015, we announced that the EC had granted marketing approval for Grünenthal's MAA for Zalviso for the management of acute moderate-to-severe post-operative pain in adult patients. In April 2016, Grünenthal completed the first commercial sale of Zalviso. Grünenthal terminated the collaboration, effective November 13, 2020. The terms of the Grünenthal Agreements were extended to May 12, 2021 to enable Grünenthal to sell down its Zalviso inventory, a right it had under the Grünenthal Agreements. Grünenthal's rights to market and sell Zalviso reverted back to us on May 12, 2021. We have not yet negotiated a New Arrangement and there can be no assurance that we will successfully enter into a New Arrangement. In June 2018, we announced that the EC had granted marketing approval of DZUVEO for the treatment of patients with moderate-to-severe acute pain in medically monitored settings. In July 2021, we entered into the DZUVEO Agreement with Aguettant.

Part of the foreign regulatory approval process includes compliance inspections of manufacturing facilities to ensure adherence to applicable regulations and guidelines. The foreign regulatory agency may delay, limit or deny marketing approval as a result of such inspections. We, our contract manufacturers, and their vendors, are all subject to preapproval and post-approval inspections at any time. The results of these inspections could impact our ability to obtain regulatory approval of DSUVIA and Zalviso in countries outside of the United States and Europe, or our ability to launch and successfully commercialize these products, once approved. In addition, results of EMA inspections could impact our ability to maintain EC approval of Zalviso and DZUVEO, and any future collaboration partner's ability to expand and sustain commercial sales of Zalviso or DZUVEO in Europe.

Outside of Europe, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and costs for us and require additional non-clinical trials or clinical trials, which could be costly and time consuming. Regulatory requirements can vary widely from country-to-country and could delay or prevent the introduction of our products in those countries. Our current clinical trial data may not be sufficient to support marketing approval or premium reimbursement in all territories. For example, we anticipate we may need comparator studies for DZUVEO in Europe to ensure premium reimbursement in certain countries. While we have obtained approval of DZUVEO in Europe, we will be substantially dependent on Aguettant to comply with regulatory requirements. If we, or our commercial partners, fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of our products will be harmed.

DSUVIA requires, and, if approved, Zalviso will require, a REMS program.

DSUVIA was approved in the United States with a REMS program. If Zalviso is approved in the United States, it will also require a REMS program. The DSUVIA REMS program includes restrictions on product distribution and use only in certified medically supervised settings. Before DSUVIA is distributed, an authorized representative from each medically supervised setting must sign an attestation that they have the ability to manage acute opioid overdose and will train all relevant staff on administration of DSUVIA, including the importance of only dispensing the product in a medically supervised setting. Therefore, REMS-certification is a key gating item to generating product revenues for DSUVIA. In addition, the REMS program for DSUVIA may significantly increase our costs to commercialize this product. While we have received pre-clearance from the FDA regarding certain aspects of the proposed required REMS program for Zalviso, we cannot predict the final REMS program to be required as part of any FDA approval of Zalviso. Depending on the extent of the REMS requirements, any U.S. launch may be delayed, the costs to commercialize Zalviso may increase substantially and the potential commercial market could be restricted. Furthermore, risks of sufentanil that are not adequately addressed through the proposed REMS program for Zalviso may also prevent or delay its approval for commercialization.

Risks Related to Our Financial Condition and Need for Additional Capital

We have incurred significant losses since our inception, anticipate that we will continue to incur significant losses in 2021 and may continue to incur losses in the future.

We have incurred significant net losses in each year since our inception in July 2005, and as of June 30, 2021, we had an accumulated deficit of $457.3 million.

We have devoted most of our financial resources to research and development, including our non-clinical development activities and clinical trials. To date, we have financed our operations primarily through the issuance of equity securities, borrowings, payments from Grünenthal, the monetization of certain future royalties and commercial sales milestones from the European sales of Zalviso by Grünenthal, funding from the Department of Defense, or DoD, and more recently with revenues from sales of DSUVIA since the commercial launch in the first quarter of 2019. The size of our future net losses will depend, in part, on the rate of future expenditures and our ability to generate revenues. We expect to continue to incur substantial expenses as we support commercialization activities for DSUVIA, manufacturing and supply activities for DZUVEO, and research and development activities for Zalviso and the PFS Products, including the FDA regulatory review of the Zalviso NDA, once resubmitted. If DSUVIA is not successfully commercialized in the U.S., if our product candidates are not successfully developed or commercialized in the U.S., or if revenues are insufficient following marketing approval, we will not achieve profitability and our business may fail. Our success is also dependent on current and future collaborations to market our products outside of the United States, which may not materialize or prove to be successful.

We have not yet generated significant product revenue and may never be profitable.

Our ability to generate revenue from commercial sales and achieve profitability depends on our ability, alone and with collaborators, to successfully complete the development of, obtain the necessary regulatory approvals for, and commercialize our products. Although we received FDA approval of DSUVIA and began the commercial launch of DSUVIA in the United States, we may never generate enough revenues from sales of DSUVIA, or our product candidates, if approved, in the United States to become profitable. Although the EC granted marketing approval of DZUVEO in June 2018, we only recently entered into the DZUVEO Agreement with Aguettant to commercialize DZUVEO in Europe and there can be no assurance that Aguettant will successfully commercialize DZUVEO. While we had a collaboration agreement with Grünenthal for commercialization of Zalviso in Europe and Australia it has been terminated, and Grünenthal was unable to achieve a level of commercial sales of Zalviso for which we were able to receive sales milestone payments. Grünenthal’s rights to market and sell Zalviso reverted back to us on May 12, 2021.

In September 2015, we consummated a monetization transaction with PDL pursuant to which we sold to PDL for $65.0 million 75% of the European royalties from sales of Zalviso and 80% of the first four commercial milestones under the Amended License Agreement, subject to a capped amount. On August 31, 2020, PDL announced it sold its royalty interest for Zalviso to SWK. As mentioned above, Grünenthal has terminated the Grünenthal Agreements and the rights reverted back to us on May 12, 2021. Per the terms of the Royalty Monetization, we are obligated to use commercially reasonable efforts to negotiate a New Arrangement. Accordingly, even if we are able to enter into a New Arrangement, and that licensee is successful in commercializing Zalviso in Europe, we will receive only a portion of any royalties until the capped amount owing under the Royalty Monetization is reached. We do not anticipate generating significant near-term revenues from DSUVIA or our product candidates, if approved, in the United States. Our ability to generate future revenues from product sales depends heavily on our success in:

- maintaining regulatory approval for DSUVIA and obtaining and maintaining regulatory approval for our product candidates in the United States; and

- launching and commercializing DSUVIA and our product candidates, if approved, in the United States by building, internally or through collaborations, an institutionally focused sales force, and launching and commercializing DZUVEO and Zalviso internationally through collaborations, which may require additional funding.

Because of the numerous risks and uncertainties associated with launching a commercial pharmaceutical product, pharmaceutical product development and the regulatory environment, we are unable to predict the timing or amount of increased expenses, or when, or if, we will be able to achieve or maintain profitability. Our expenses could increase beyond expectations if we are delayed in receiving regulatory approval for our product candidates in the United States, or if we are required by the FDA to complete activities in addition to those we currently anticipate or have already completed.

We anticipate continuing to incur significant costs associated with commercializing DSUVIA in the United States. Even if we are able to generate revenues from the sale of DSUVIA or our product candidates, if approved, in the United States, we may not become profitable and may need to obtain additional funding to continue operations.

Future sales of DSUVIA to the DoD are not predictable, may occur on an irregular basis and may not meet our expectations due to various U.S. government-related factors that are beyond our control and into which we have little to no visibility, including the timing and extent of future U.S. military deployments. If DoD spending on DSUVIA does not meet our expectations, it could adversely affect our expected results of operations, financial condition and liquidity.

In April 2020, DSUVIA achieved Milestone C approval by the DoD, a decision that clears the path for the DoD to begin placing orders for DSUVIA. In September 2020, we announced that DSUVIA was added to the DoD Joint Deployment Formulary, a core list of pharmaceutical products that are designated for deploying military units across all service branches. Future sales of DSUVIA to the DoD are not predictable, may occur on an irregular basis, and may not meet our expectations due to various U.S. government-related factors that are beyond our control and into which we have little to no visibility, including the timing and extent of future U.S. military deployments. Even if we do generate revenue from such sales, we may never generate revenue that is significant or predictable, which could impair our value and our ability to raise capital, expand our business or continue our operations. The placement of new orders by the DoD is, among other things, contingent upon overall U.S. government policies, budget and appropriation decisions and processes which are driven by numerous factors, including geo-political events, deployment of military units, macroeconomic conditions, and the ability of the U.S. government to enact relevant legislation, such as appropriations bills and accords on the debt ceiling. Our expectations about the timing and size of initial stocking orders for U.S. Army sets, kits and outfits, or SKOs, and other orders by the DoD are based on our understanding of troop deployment schedules. If DoD spending on DSUVIA does not meet our expectations, it could have a material adverse effect on our expected results of operations, financial condition and liquidity.

We have been substantially dependent on Grünenthal to successfully commercialize Zalviso in Europe and they have terminated their collaboration agreement with us.

Under our agreements with Grünenthal, we granted Grünenthal rights to commercialize Zalviso in Europe for human use in pain treatment within, or dispensed by, hospitals, hospices, nursing homes and other medically supervised settings. In September 2015, the EC granted marketing approval for Grünenthal's MAA for Zalviso for the management of acute moderate-to-severe post-operative pain in adult patients, and Grünenthal began its European launch of Zalviso with the first commercial sale occurring in April 2016. Grünenthal terminated the collaboration, effective November 13, 2020. The terms of the Grünenthal Agreements were extended to May 12, 2021 to enable Grünenthal to sell down its Zalviso inventory, a right it had under the Grünenthal Agreements. Grünenthal's rights to market and sell Zalviso reverted back to us on May 12, 2021.

During the pilot and launch phases in the various European countries, Grünenthal reported certain issues from HCPs with the initial set up of the Zalviso controllers before being given to patients for use. To address the issues, we have assisted Grünenthal with implementing additional training for HCPs and we have revised the controller software. Controllers with the revised software, which were delivered in December 2016, have undergone extensive bench testing and we believe we have successfully addressed the issues as presented. Additional devices were delivered beginning in early 2017. Controllers with the U.S. version of the revised software were also used in the IAP312 clinical study that was initiated in September 2016. There can be no assurance that the issues identified in the initial pilot and launch phases by Grünenthal will not have a material adverse impact on future sales of Zalviso in Europe. Further, if new issues occur, there may be a material adverse impact on the future sales of Zalviso in Europe which may have a negative impact on future revenues received and recognized by us.

We have not realized the expected benefits from our collaboration with Grünenthal, and may not realize the expected benefits from any New Arrangement, due to a number of important factors, including:

- The timing and amount of any payments we may receive under our agreements will depend on, among other things, the efforts, allocation of resources, and successful commercialization of Zalviso by any future collaboration partner in Europe;
- Grünenthal changed the focus of its commercialization efforts to pursue higher-priority programs and any future collaboration partner may do the same;
- Grünenthal stopped its commercialization efforts in countries where it had the sole right to commercialize Zalviso, requiring us to find another collaboration partner for Zalviso in Europe; and
- Grünenthal has terminated its agreements with us, and any future collaboration partner may also terminate any future agreement with us, adversely affecting our potential revenue from Zalviso;

Any failures in commercialization of Zalviso outside the United States could have a material adverse impact on our business, including an adverse impact on the commercialization of DSUVIA or the development of Zalviso in the United States, if related to issues underlying the sufentanil sublingual tablet technology, safety or efficacy. Additionally, we agreed to certain representations and covenants relating to the Grünenthal Agreements under our agreements with PDL, and, if we breach those representations or covenants, we may become subject to indemnification claims by SWK (assignee of PDL) and liable to SWK for its indemnifiable losses relating to such breaches. The amount of such losses could be material and could have a material adverse impact on our business.

We will be substantially dependent on Aguettant to successfully commercialize DZUVEO in Europe.*

In June 2018, the EC granted marketing approval for DZUVEO and in July 2021 we entered into the DZUVEO Agreement with Aguettant to commercialize DZUVEO in Europe. We will be substantially dependent on Aguettant to successfully commercialize DZUVEO in Europe. Any failures in the commercialization of DZUVEO in Europe could have a significant adverse impact on our revenues and operating results.

The DZUVEO Agreement requires us to support the manufacturing and supply of DZUVEO for Aguettant. In addition, we anticipate we may need comparator studies in Europe to ensure premium reimbursement in certain countries. Our inability to profitably manufacture and supply DZUVEO to Aguettant, or to successfully complete these additional comparator studies and obtain premium reimbursement in certain countries, may prevent, limit or delay commercialization and any associated future revenues from DZUVEO in Europe.

We have limited experience commercializing DSUVIA, which may make it difficult to predict our future performance or evaluate our business and prospects.

Since inception, our operations have been primarily focused on developing our technology and undertaking pharmaceutical development and clinical trials for DSUVIA and Zalviso, understanding the market potential for DSUVIA and Zalviso, and preparing for the commercialization of DSUVIA and the potential commercialization of Zalviso in the United States. We launched commercialization efforts for DSUVIA in February 2019. As a result of our limited commercialization experience, any predictions that are made about our future performance, or viability, or evaluation of our business and prospects, may not be accurate.

We will require additional capital and may be unable to raise capital, which would force us to delay, reduce or eliminate our commercialization efforts and product development programs and could cause us to cease operations.

Launch of a commercial pharmaceutical product and pharmaceutical development activities can be time consuming and costly. We expect to incur significant expenditures in connection with supporting our ongoing commercialization activities for DSUVIA, manufacturing and supply activities for DZUVEO, and research and development activities for Zalviso and the PFS Products, including the FDA regulatory review of the Zalviso NDA, once resubmitted. While we believe we have sufficient capital resources to continue planned operations for at least the next twelve months, we will need additional capital to pursue full commercialization of DSUVIA and our product candidates, if approved.

Clinical trials, regulatory reviews, and the launch of commercial product are expensive activities. In addition, commercialization costs for DSUVIA and our product candidates, if approved, in the United States may be significantly higher than estimated as a result of technical difficulties or otherwise. Revenues may be lower than expected and costs to produce such revenues may exceed those revenues. We will need to seek additional capital to continue operations. Such capital demands could be substantial. In the future, we may seek to sell additional equity securities, including under the Sales Agreement with Cantor, and debt securities, monetize or securitize certain assets including future royalty streams and milestones, refinance our loan agreement, obtain a revolving credit facility, enter into product development, license or distribution agreements with third parties, or divest DSUVIA, DZUVEO or Zalviso. Such arrangements may not be available on favorable terms, if at all.

Future events and circumstances, including those beyond our control, may cause us to consume capital more rapidly than we currently anticipate. Furthermore, any product development, licensing, distribution or sale agreements that we enter into may require us to relinquish valuable rights. We may not be able to obtain sufficient additional funding or enter into a strategic transaction in a timely manner. If adequate funds are not available, we would be required to reduce our workforce, reduce the scope of, or cease, the commercial launch of DSUVIA, or the development of our product candidates in advance of the date on which we exhaust our cash resources to ensure that we have sufficient capital to meet our obligations and continue on a path designed to preserve stockholder value.

Securing additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to commercialize DSUVIA or develop our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we are unable to raise additional capital when required or on acceptable terms, we may be required to:

- significantly scale back or discontinue the commercialization of DSUVIA, or the development of our product candidates;
- seek additional corporate partners for Zalviso on terms that might be less favorable than might otherwise be available;

- seek corporate partners for DSUVIA/DZUVEO on terms that might be less favorable than might otherwise be available; or

- relinquish, or license on unfavorable terms, our rights to technologies or products that we otherwise would seek to develop or commercialize ourselves.

To fund our operations, we may sell additional equity securities, which may result in dilution to our stockholders, or debt securities, which may impose restrictions on our business.

We expect that significant additional capital will be needed in the future to continue our planned operations. In order to raise additional funds to support our operations, we may sell additional equity securities, including under the Controlled Equity Offering℠ Sales Agreement, or the ATM Agreement, with Cantor Fitzgerald & Co., or Cantor, as agent. We may sell common stock, convertible securities, or other equity securities in one or more transactions at prices and in a manner we determine from time to time. Selling additional equity securities may result in dilution to our existing stockholders and new investors may be materially diluted by subsequent sales. Incurring additional indebtedness, including through the sale of debt securities, would result in increased fixed payment obligations and could also result in additional restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions, such as minimum cash balances, that could adversely impact our ability to conduct our business. Sales of equity or debt securities may also provide new investors with rights superior to our existing stockholders. If we are unable to expand our operations or otherwise capitalize on our business opportunities, our business, financial condition and results of operations could be materially adversely affected, and we may not be able to meet our debt service obligations.

In addition, worsening economic conditions and other adverse effects or developments relating to the ongoing COVID-19 pandemic may negatively affect the market price of our stock, regardless of our actual operating performance. The market price for our common stock is likely to continue to be volatile, particularly due to the ongoing COVID-19 pandemic, and subject to significant price and volume fluctuations in response to market, industry and other factors. If additional funding is not available on favorable terms, if at all, due to these factors, we may not be able to obtain sufficient additional funding to support our operations.

The terms of our loan agreement with Oxford may restrict our current and future operations, particularly our ability to respond to changes in business or to take certain actions, including to pay dividends to our stockholders.

On May 30, 2019, we entered into the Loan Agreement with Oxford Finance LLC, or Oxford, a Delaware limited liability company, as the Lender. The Loan Agreement contains, and any future indebtedness we incur will likely contain, a number of restrictive covenants that impose operating restrictions, including restrictions on our ability to engage in acts that may be in our best long-term interests. The Loan Agreement includes covenants that, among other things, restrict our ability to (i) declare dividends or redeem or repurchase equity interests; (ii) incur additional liens; (iii) make loans and investments; (iv) incur additional indebtedness; (v) engage in mergers, acquisitions, and asset sales; (vi) transact with affiliates; (vii) undergo a change in control; (viii) add or change business locations; and (ix) engage in businesses that are not related to our existing business. The Loan Agreement also requires that we at all times maintain unrestricted cash of not less than $5.0 million.

A breach of any of these covenants could result in an event of default under the Loan Agreement. Upon the occurrence of such an event of default, a default interest rate of an additional 5% may be applied to the outstanding loan balances and all outstanding obligations under the Loan Agreement can be declared to be immediately due and payable If our indebtedness is accelerated, we cannot assure you that we will have sufficient assets to repay the indebtedness. The restrictions and covenants in the Loan Agreement and any future financing agreements may adversely affect our ability to finance future operations or capital needs or to engage in other business activities.

We might be unable to service our existing debt due to a lack of cash flow and might be subject to default.

As of June 30, 2021, we had approximately $17.2 million of accrued debt under the Loan Agreement. The Loan Agreement has a scheduled maturity date of June 1, 2023 and is secured by a first priority security interest in substantially all of our assets, with the exception of our intellectual property and those assets sold under the Royalty Monetization, where the security interest is limited to proceeds of intellectual property if it is licensed or sold.

If we do not make the required payments when due, either at maturity, or at applicable installment payment dates, or if we breach the agreement or become insolvent, the Lender could elect to declare all amounts outstanding, together with accrued and unpaid interest, and other payments, to be immediately due and payable. Additional capital may not be available on terms acceptable to us, or at all. Even if we were able to repay the full amount in cash, any such repayment could leave us with little or no working capital for our business. If we are unable to repay those amounts, the Lender will have a first claim on our assets pledged under the Loan Agreement. If the lender should attempt to foreclose on the collateral, it is unlikely that there would be any assets remaining after repayment in full of such secured indebtedness. Any default under the Loan Agreement and resulting foreclosure would have a material adverse effect on our financial condition and our ability to continue our operations.

Risks Related to Our Reliance on Third Parties

We rely on third party manufacturers to produce commercial supplies of DSUVIA in the United States, commercial supplies of Zalviso in Europe, and clinical supplies of Zalviso in the United States, and will rely on third party manufacturers to produce DZUVEO for Aguettant and on Aguettant to produce commercial supplies of the PFS Products, if approved, in the United States. The failure of third-party manufacturers to provide us with adequate commercial and clinical supplies could result in a material adverse effect on our business.*

Third party manufacturers produce commercial and clinical supplies of our products and product candidates. Reliance on third party manufacturers entails many risks including:

- the inability to meet our product specifications and quality requirements consistently;
- a delay or inability to procure or expand sufficient manufacturing capacity;
- manufacturing and product quality issues related to scale-up of manufacturing;
- costs and validation of new equipment and facilities required for scale-up;
- a failure to maintain in good order our production and manufacturing equipment for our products;
- a failure to comply with cGMP and similar foreign standards;
- the inability to negotiate manufacturing or supply agreements with third parties under commercially reasonable terms;
- termination or nonrenewal of manufacturing or supply agreements with third parties in a manner or at a time that is costly or damaging to us;
- the reliance on a limited number of sources, and in some cases, single sources for product components, such that if we are unable to secure a sufficient supply of these product components, we will be unable to manufacture and sell our products in a timely fashion, in sufficient quantities or under acceptable terms;
- the lack of qualified backup suppliers for those components that are currently purchased from a sole or single source supplier;
- operations of our third-party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier, or government orders related to the COVID-19 pandemic;
- carrier disruptions or increased costs that are beyond our control; and
- the failure to deliver our products under specified storage conditions and in a timely manner.

Any of these events could lead to stock outs, inability to successfully commercialize our products, clinical trial delays, or failure to obtain regulatory approval. Some of these events could be the basis for FDA action, including injunction, recall, seizure, or total or partial suspension of production.

In addition, the DZUVEO Agreement requires us to manufacture and supply DZUVEO to Aguettant. As mentioned above, we were obligated to manufacture and supply Zalviso under the Grünenthal Agreements for use in Europe and their other licensed territories and will likely be required to do so under any New Arrangement. If we are unable to establish a reliable commercial supply of DZUVEO for Aguettant, and, if a New Arrangement is entered into, Zalviso for Europe, we may be unable to satisfy our obligations under the DZUVEO Agreement or any New Arrangement in a timely manner or at all, and we may, as a result, be in breach of such agreements. If any such breach, or other breach, were to be material and remain uncured, it could result in termination of the agreement, which in turn could, in the case of a New Arrangement, result in us being responsible for indemnification of losses suffered by SWK (assignee of PDL) under the Royalty Monetization. If any of these events were to occur, our business would be materially adversely affected.

We rely on limited sources of supply for the active pharmaceutical ingredient, or API, of DSUVIA and Zalviso and any disruption in the chain of supply may cause a delay in supplying DSUVIA and Zalviso.

Currently we only have one supplier qualified as a vendor for the manufacture of DSUVIA, known as DZUVEO in Europe, and Zalviso with the FDA and EMA, respectively. If supply from the approved vendor is interrupted, there could be a significant disruption in commercial supply. For example, our API provider for DSUVIA is changing its process for manufacturing our drug, which could impact our commercial supply of API for DSUVIA. This change in process requires a regulatory submission to the FDA. The European Health Authority has approved the change in process for both DZUVEO and Zalviso in the EU. In the U.S., a regulatory submission has been submitted to support the use of the API made with the new manufacturing process, but there is no guarantee that the FDA will approve the submission. For example, in July 2019, we received notice from the FDA that a deficiency in the API manufacturer's drug master file, or DMF, will need to be addressed before the submission can be approved. The API manufacturer responded to the FDA's DMF deficiency notice for the new manufacturing process, and we resubmitted the Supplemental NDA seeking approval of use of the new manufacturing process API. Any alternate vendor would need to be qualified through an NDA supplement and/or an MAA variation which could result in delays. The FDA or other regulatory agencies outside of the United States may also require additional trials if a new sufentanil supplier is relied upon for commercial production.

Manufacture of sufentanil sublingual tablets requires specialized equipment and expertise.

Ethanol, which is used in the manufacturing process for our sufentanil sublingual tablets, is flammable, and sufentanil is a highly potent, Schedule II controlled substance. These factors necessitate the use of specialized equipment and facilities for manufacture of sufentanil sublingual tablets. There are a limited number of facilities that can accommodate our manufacturing process and we need to use dedicated equipment throughout development and commercial manufacturing to avoid the possibility of cross-contamination. If our equipment breaks down or needs to be repaired or replaced, it may cause significant disruption in clinical or commercial supply, which could result in delay in the process of obtaining approval for or sale of our products. Furthermore, we are using one manufacturer to produce our sufentanil sublingual tablets. Any problems with our existing facility or equipment, including ongoing expansion, may impair our ability to successfully commercialize DSUVIA or Zalviso, if approved, complete our clinical trials and increase our cost.

Manufacturing issues may arise that could delay or increase costs related to commercialization, product development and regulatory approval.*

We have relied, and will continue to rely, on contract manufacturers, component fabricators and third-party service providers to produce the necessary DSUVIA single-dose applicator, or SDA, and Zalviso devices for the commercial marketplace. We currently outsource manufacturing and packaging of the DSUVIA SDA and the controller, dispenser and cartridge components of the Zalviso device to third parties and intend to continue to do so. Some of these component purchases were made and will continue to be made utilizing short-term purchase agreements and we may not be able to enter into long-term agreements for commercial supply of DSUVIA, DZUVEO or Zalviso devices with each of the third-party manufacturers or may be unable to do so on acceptable terms. In addition, we have encountered and may continue to encounter production issues with our current or future contract manufacturers and other third party service providers, including the reliability of the production equipment, quality of the components produced, their inability to meet demand or other unanticipated delays including scale-up and automating processes, which could adversely impact our ability to supply our customers with DSUVIA, Zalviso and DZUVEO in Europe, and, if approved, Zalviso in the U.S. and any other foreign territories.

As we scale up manufacturing of DSUVIA and Zalviso, if approved, and conduct required stability testing, product, packaging, equipment and process-related issues may require refinement or resolution. For example, as we scale up, we may identify significant issues which could result in failure to maintain regulatory approval of DSUVIA, increased scrutiny by regulatory agencies, delays in clinical program and regulatory approval, increases in our operating expenses, or failure to obtain approval for our product candidates in the United States.

We have built out a suite within our CMO’s production facility in Cincinnati, Ohio that serves as a manufacturing facility for clinical and commercial supplies of sufentanil sublingual tablets. Late-stage development and manufacture of registration stability lots, which were utilized in clinical trials, were manufactured at this location. While we produced a number of commercial lots to support Grünenthal’s launch in Europe, our experience is limited, which impacted our ability to deliver commercial supplies to Grünenthal on a timely basis, and may in the future impact our ability to deliver commercial supplies under any New Arrangement, if required, on a timely basis.

In January 2013, we entered into an agreement with a CMO to manufacture, supply, and provide certain validation and stability services with respect to Zalviso for potential sales in the United States, Canada, Mexico and other countries, subject to agreement by the parties to any additional fees for such other countries. On August 22, 2017, we entered into an amendment to this agreement to manufacture, supply, and provide certain validation and stability services with respect to DSUVIA for sales in the United States, and potential sales in Canada and Mexico, and other countries. There is no guarantee that our CMO’s services will be satisfactory or that they will continue to meet the strict regulatory guidelines of the FDA or other foreign regulatory agencies. If our CMO cannot provide us with an adequate supply of sufentanil sublingual tablets, we may be required to pursue alternative sources of manufacturing capacity. Switching or adding commercial manufacturing capability can involve substantial cost and require extensive management time and focus, as well as additional regulatory filings which may result in significant delays. In addition, there is a natural transition period when a new manufacturing facility commences work. As a result, delays may occur, which can materially impact our ability to meet our desired commercial timelines, thereby increasing our costs and reducing our ability to generate revenue.

The facilities of any of our future manufacturers of sufentanil-containing sublingual tablets must be approved by the FDA or the relevant foreign regulatory agency, such as the EMA, before commercial distribution from such manufacturers occurs. We do not fully control the manufacturing process of sufentanil sublingual tablets and are completely dependent on these third-party manufacturing partners for compliance with the FDA or other foreign regulatory agency's requirements for manufacture. In addition, although our third-party manufacturers are well-established commercial manufacturers, we are dependent on their continued adherence to cGMP manufacturing and acceptable changes to their process. If our manufacturers do not meet the FDA or other foreign regulatory agency's strict regulatory requirements, they will not be able to secure FDA or other foreign regulatory agency approval for their manufacturing facilities. Although European inspectors have approved our tablet manufacturing site, our third-party manufacturing partner is responsible for maintaining compliance with the relevant foreign regulatory agency's requirements. If the FDA or the relevant foreign regulatory agency does not approve these facilities for the commercial manufacture of sufentanil sublingual tablets, we will need to find alternative suppliers, which would result in significant delays in obtaining FDA approval for Zalviso, and other foreign regulatory agency approval of DSUVIA/DZUVEO and Zalviso outside Europe. These challenges may have a material adverse impact on our business, results of operations, financial condition and prospects.

We may not be able to establish additional sources of supply for sufentanil-containing sublingual tablets or device manufacture. Such suppliers are subject to FDA and other foreign regulatory agency's regulations requiring that materials be produced under cGMPs or Quality System Regulations, or QSR, or in ISO 13485 accredited manufacturers, and subject to ongoing inspections by regulatory agencies. Failure by any of our suppliers to comply with applicable regulations may result in delays and interruptions to our product supply while we seek to secure another supplier that meets all regulatory requirements. In addition, if we are unable to establish a reliable commercial supply of Zalviso for Europe, we may be unable to satisfy our obligations under any New Arrangement, if required, in a timely manner or at all, and we may, as a result, be in breach of any New Arrangement.

For DSUVIA, we currently package the finished goods under a manual process and would package DZUVEO in the same manner. The capacity and cost to package the goods under this manual process are not optimal to support successful future sales of DSUVIA and DZUVEO. We have purchased and installed an automated filling and packaging line to support increased capacity packaging for DSUVIA and DZUVEO. Despite the delays due to the impact of COVID-19, we have now completed the acquisition and installation of this line; however, there can be no assurance that we will be able to obtain the necessary regulatory approvals to manufacture product on this line.

We rely on third parties to conduct, supervise and monitor our clinical trials, and if those third parties perform in an unsatisfactory manner, it may harm our business.

We utilized contract research organizations, or CROs, for the conduct of the Phase 2 and 3 clinical trials of DSUVIA, as well as our Phase 3 clinical program for Zalviso. We rely on CROs, as well as clinical trial sites, to ensure the proper and timely conduct of our clinical trials and document preparation. While we have agreements governing their activities, we have limited influence over their actual performance. We have relied and plan to continue to rely upon CROs to monitor and manage data for our post-approval clinical programs for DSUVIA and any FDA-required clinical programs for Zalviso, as well as the execution of nonclinical and clinical trials. We control only certain aspects of our CROs' activities. Nevertheless, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs does not relieve us of our regulatory responsibilities.

We, and our CROs, are required to comply with the FDA's current good clinical practices, or cGCPs, which are regulations and guidelines enforced by the FDA for all product candidates in clinical development. The FDA enforces these cGCPs through periodic inspections of trial sponsors, principal investigators and clinical trial sites. If we or our CROs fail to comply with applicable cGCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving our marketing applications. Upon inspection, the FDA may determine that our clinical trials do not comply with cGCPs. Accordingly, if our CROs or clinical trial sites fail to comply with these regulations, we may be required to repeat clinical trials, which would delay the regulatory process.

Our CROs are not our employees, and we cannot control whether or not they devote sufficient time and resources to our ongoing clinical and nonclinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials, or other drug development activities which could harm our competitive position. We face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by CROs, which may allow our potential competitors to access our proprietary technology. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements, or for any other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize Zalviso. As a result, our financial results and the commercial prospects for Zalviso, if approved, would be harmed, our costs could increase, and our ability to generate revenues could be delayed.

Risks Related to Our Business Operations and Industry

Failure to receive required quotas of controlled substances or comply with the Drug Enforcement Agency regulations, or the cost of compliance with these regulations, may adversely affect our business.

Our sufentanil-based products are subject to extensive regulation by the DEA, due to their status as scheduled drugs. Sufentanil is classified as a Schedule II controlled substance, considered to present a high risk of abuse. The manufacture, shipment, storage, sale and use of controlled substances are subject to a high degree of regulation, including security, record-keeping and reporting obligations enforced by the DEA and also by comparable state agencies. In addition, our contract manufacturers are required to maintain relevant licenses and registrations. This high degree of regulation can result in significant compliance costs, which may have an adverse effect on the commercialization of DSUVIA and the development and commercialization of Zalviso, if approved.

The DEA limits the availability and production of all Schedule II controlled substances, including sufentanil, through a quota system. The DEA requires substantial evidence and documentation of expected legitimate medical and scientific needs before assigning quotas to manufacturers. Our contract manufacturers apply for quotas on our behalf. We will need significantly greater amounts of sufentanil to successfully commercialize DSUVIA, to support European commercialization of DZUVEO and Zalviso, and to commercialize Zalviso, if approved in the United States. Any delay by the DEA in establishing the procurement quota, reduction in our quota for sufentanil, failure to increase our quota over time to meet anticipated increases in demand, or refusal by the DEA to establish the procurement quota could delay or stop the commercial sale of our approved products or the clinical development of Zalviso in the United States. This, in turn, could have a material adverse effect on our business, results of operations, financial condition and prospects.

Our relationships with clinical investigators, health care professionals, consultants, commercial partners, third-party payers, hospitals, and other customers are subject to applicable anti-kickback, fraud and abuse and other healthcare laws, which could expose us to significant penalties.

Healthcare providers, including physicians, and others play a primary role in the recommendation and prescribing of any products for which we may obtain marketing approval. Our business operations and arrangements with investigators, healthcare professionals, consultants, commercial partners, hospitals, third-party payers and customers may expose us to broadly applicable fraud and abuse and other healthcare laws. These laws may constrain the business or financial arrangements and relationships through which we research, market, sell and distribute the products for which we obtain marketing approval. Applicable federal and state healthcare laws include, but are not limited to, the following:

- the federal healthcare Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid;

- the federal civil and criminal false claims laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, to the federal government, claims for payment or approval that are false or fraudulent or from knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which, among other things, imposes criminal liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payer (e.g., public or private) and knowingly or willfully falsifying, concealing, or covering up by any trick or device a material fact or making any materially false statement in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, which impose certain obligations, including mandatory contractual terms, on covered healthcare providers, health plans and clearinghouses, and their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, as well as their covered subcontractors with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- foreign laws, regulations, standards and regulatory guidance which govern the collection, use, disclosure, retention, security and transfer of personal data, including the European Union General Data Privacy Regulation, or GDPR, which introduces strict requirements for processing personal data of individuals within the European Union;

- the federal transparency law, enacted as part of the Affordable Care Act, and its implementing regulations, which requires certain manufacturers of drugs, devices, biologicals and medical supplies to report annually to the CMS information related to payments and other transfers of value provided to physicians, (defined to include, doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report such information regarding payments and other transfers of value made to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives during the previous year;

- analogous state laws that may apply to our business practices, including but not limited to, state laws that require pharmaceutical companies to implement compliance programs and/or comply with the pharmaceutical industry's voluntary compliance guidelines; state laws that impose restrictions on pharmaceutical companies' marketing practices and require manufacturers to track and file reports relating to pricing and marketing information, which requires tracking and reporting gifts, compensation and other remuneration and items of value provided to healthcare professionals and entities, state and local laws that require the registration of pharmaceutical sales representatives, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways, with differing effects; and

- the federal Foreign Corrupt Practices Act of 1977, United Kingdom Bribery Act 2010 and other similar anti-bribery laws in other jurisdictions which generally prohibit companies and their intermediaries from providing money or anything of value to officials of foreign governments, foreign political parties, or international organizations with the intent to obtain or retain business or seek a business advantage.

Recently, there has been a substantial increase in anti-bribery law enforcement activity by U.S. regulators, with more frequent and aggressive investigations and enforcement proceedings by both the Department of Justice and the SEC. A determination that our operations or activities are not, or were not, in compliance with United States or foreign laws or regulations could result in the imposition of substantial fines, interruptions of business, loss of supplier, vendor or other third-party relationships, termination of necessary licenses and permits, and other legal or equitable sanctions. Other internal or government investigations or legal or regulatory proceedings, including lawsuits brought by private litigants, may also follow as a consequence.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws. If our operations are found to be in violation of any of these or any other healthcare regulatory laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, increased losses and diminished profits, additional oversight and reporting obligations if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations any of which could adversely affect our ability to operate our business and our financial results. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses or divert our management's attention from the operation of our business.

In order to supply the Zalviso device to any future collaborator for commercial sales in Europe, we must maintain conformity of our quality system to applicable ISO standards and must comply with applicable European laws and directives.

We underwent a Conformité Européenne approval process for the Zalviso device, more commonly known as a CE Mark approval process. We received CE Mark approval in December 2014, which permits the commercial sale of the Zalviso device in Europe. In connection with the CE Mark approval, we were also granted International Standards Organization, or ISO, 13485:2003 certification of our quality management system in November 2014. This is an internationally recognized quality standard for medical devices. The CE Mark was originally issued by the British Standards Institution, or BSI, a Notified Body, or NB, located in the United Kingdom, or U.K., or BSI-U.K. The CE Mark file and certification has been transferred to the Netherlands NB of BSI, or BSI-NL, to mitigate the uncertainty with regards to Brexit. The ISO certification issued through BSI-U.K. was recently upgraded to the latest version of the standard, ISO 13485:2016 through BSI-U.K. and remains in effect. BSI ISO 13485:2016 certification recognizes that consistent quality policies and procedures are in place for the development, design and manufacturing of medical devices. The certification indicates that we have successfully implemented a quality system that conforms to ISO 13485 standards for medical devices. Certification to this standard is one of the key regulatory requirements for a CE Mark in the EU and European Economic Area (which includes the 27 EU member states as well as Norway, Iceland and Liechtenstein), or EEA, as well as to meet equivalent requirements in other international markets. The certification applies to the Redwood City, California location which designs, manufactures and distributes finished medical devices, and includes critical suppliers. If we fail to remain in compliance with applicable European laws and directives, we would be unable to continue to affix the CE Mark to our Zalviso device, which would prevent any future collaboration partner from selling these devices within the EU and EEA.

Significant disruptions of our information technology systems or data security incidents could result in significant financial, legal, regulatory, business and reputational harm to us.

We are increasingly dependent on information technology systems and infrastructure, including mobile technologies, to operate our business. In the ordinary course of our business, we collect, store, process and transmit large amounts of sensitive information, including intellectual property, proprietary business information, personal information and other confidential information. It is critical that we do so in a secure manner to maintain the confidentiality, integrity and availability of such sensitive information. We have also outsourced elements of our operations (including elements of our information technology infrastructure) to third parties, and as a result, we manage a number of third-party vendors who may or could have access to our computer networks or our confidential information. In addition, many of those third parties in turn subcontract or outsource some of their responsibilities to third parties. While all information technology operations are inherently vulnerable to inadvertent or intentional security breaches, incidents, attacks and exposures, the accessibility and distributed nature of our information technology systems, and the sensitive information stored on those systems, make such systems potentially vulnerable to unintentional or malicious internal and external attacks on our technology environment. Potential vulnerabilities can be exploited from inadvertent or intentional actions of our employees, third-party vendors, business partners, or by malicious third parties. Attacks of this nature are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives (including, but not limited to, industrial espionage) and expertise, including organized criminal groups, "hacktivists," nation states and others. In addition to the extraction of sensitive information, such attacks could include the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. In addition, the prevalent use of mobile devices increases the risk of data security incidents.

Significant disruptions of our third-party vendors' and/or business partners' information technology systems or other similar data security incidents could adversely affect our business operations and result in the loss, misappropriation, and/or unauthorized access, use or disclosure of, or the prevention of access to, sensitive information, which could result in financial, legal, regulatory, business and reputational harm to us. In addition, information technology system disruptions, whether from attacks on our technology environment or from computer viruses, natural disasters, terrorism, war and telecommunication and electrical failures, could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

There is no way of knowing with certainty whether we have experienced any data security incidents that have not been discovered. While we have no reason to believe this to be the case, attackers have become very sophisticated in the way they conceal access to systems, and many companies that have been attacked are not aware that they have been attacked. Any event that leads to unauthorized access, use or disclosure of personal information, including but not limited to personal information regarding our patients or employees, could disrupt our business, harm our reputation, compel us to comply with applicable federal and state breach notification laws and foreign law equivalents, subject us to time consuming, distracting and expensive litigation, regulatory investigation and oversight, mandatory corrective action, require us to verify the correctness of database contents, or otherwise subject us to liability under laws, regulations and contractual obligations, including those that protect the privacy and security of personal information. This could result in increased costs to us, and result in significant legal and financial exposure and/or reputational harm. In addition, any failure or perceived failure by us or our vendors or business partners to comply with our privacy, confidentiality or data security-related legal or other obligations to third parties, or any further security incidents or other inappropriate access events that result in the unauthorized access, release or transfer of sensitive information, which could include personally identifiable information, may result in governmental investigations, enforcement actions, regulatory fines, litigation, or public statements against us by advocacy groups or others, and could cause third parties, including clinical sites, regulators or current and potential partners, to lose trust in us or we could be subject to claims by third parties that we have breached our privacy- or confidentiality-related obligations, which could materially and adversely affect our business and prospects. Moreover, data security incidents and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above. While we have implemented security measures intended to protect our information technology systems and infrastructure, there can be no assurance that such measures will successfully prevent service interruptions or security incidents.

Business interruptions could delay our operations and sales efforts.

Our headquarters is located in the San Francisco Bay Area, near known earthquake fault zones and is vulnerable to significant damage from earthquakes. Our contract manufacturers, suppliers, clinical trial sites and local and national transportation vendors are all subject to business interruptions due to weather, outbreaks of pandemic diseases, natural disasters, or man-made incidents. We are also vulnerable to other types of natural disasters and other events that could disrupt our operations. If any of these events occurred and prevented us or third parties on which we rely from using all or a significant portion of our or their facilities, it may be difficult or, in certain cases, impossible for us to continue our business and operations for a substantial period of time.

We do not carry insurance for earthquakes or other natural disasters, and we may not carry sufficient business interruption insurance to compensate us for losses that may occur. Any losses or damages we incur could have a material adverse effect on our business operations.

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on principal members of our executive team, the loss of whose services may adversely impact the achievement of our objectives. While we have entered into offer letters with each of our executive officers, any of them could leave our employment at any time, as all of our employees are "at will" employees. Recruiting and retaining qualified scientific, manufacturing, and commercial personnel will also be critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. There is currently a shortage of skilled executives in our industry, which is likely to continue. As a result, competition for skilled personnel is intense and the turnover rate can be high. In addition, failure to succeed in clinical trials, or delays in the regulatory approval process, may make it more challenging to recruit and retain qualified personnel. The inability to recruit or loss of the services of any executive or key employee might impede the progress of our research, development and commercialization objectives.

We may acquire companies, product candidates or products or engage in strategic transactions, which could divert our management's attention and cause us to incur various costs and expenses.

We may acquire or invest in companies, product candidates or products that we believe could complement or expand our business or otherwise offer growth opportunities. The pursuit of potential acquisitions or investments may divert the attention of management and has caused, and in the future may cause, us to incur various costs and expenses in identifying, investigating, and pursuing them, whether or not they are consummated. We may not be able to identify desirable acquisitions or investments or be successful in completing or realizing anticipated benefits from such transactions. In addition, the acquisition of product candidates and products is a highly competitive area, and many other companies are pursuing the same or similar product candidates to those that we may consider attractive. Larger companies with more well-established and diverse revenue streams may have a competitive advantage over us due to their size, financial resources and more extensive clinical development and commercialization capabilities.

In addition, we may receive inquiries relating to potential strategic transactions, including collaborations, licenses, and acquisitions. Such potential transactions may divert the attention of management and may cause us to incur various costs and expenses in investigating and evaluating such transactions, whether or not they are consummated.

We face potential product liability claims, and, if such claims are successful, we may incur substantial liability.

Commercial sales of DSUVIA and Zalviso expose us to the risk of product liability claims. Product liability claims might be brought against us by patients, health care providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation;
- costs due to related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- the inability to commercialize our products; and
- decreased demand for our products.

Our current product liability insurance coverage may not be sufficient to reimburse us for any expenses or losses we may suffer. In addition, our current product liability insurance contains an exclusion related to any claims related to our products from a governmental body, or payer, or those claims arising from a multi-plaintiff action for bodily injury or property damage. Multi-plaintiff claims caused by product defects are covered. This exclusion does not apply to any bodily injury claim related to our products made by an individual. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated adverse effects. A successful product liability claim, or series of claims, brought against us could cause our stock price to decline and, if judgments are excluded from our insurance coverage or exceed our insurance coverage, could adversely affect our results of operations and business. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability.

Our insurance coverage included the sale of Zalviso to our former commercial partner, Grünenthal, and will likely include the sale of Zalviso by any future commercial partner. We intend to commercialize and promote DZUVEO in Europe with a strategic partner which may result in further expansion of our insurance coverage to include sales of DZUVEO in Europe. There can be no assurance that such coverage will be adequate to protect us against any future losses due to liability.

Our employees, independent contractors, principal investigators, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk that our employees, independent contractors, investigators, consultants, commercial partners and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct that violates (1) regulations implemented by the FDA and similar foreign regulatory bodies; (2) laws requiring the reporting of true, complete and accurate information to such regulatory bodies; (3) healthcare fraud and abuse laws of the United States and similar foreign fraudulent misconduct laws; and (4) laws requiring the reporting of financial information or data accurately. The promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry are subject to extensive laws designed to prevent misconduct, including fraud, kickbacks, self-dealing and other abusive practices. These laws may restrict or prohibit a wide range of pricing, discounting, marketing, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. It is not always possible to identify and deter employee and other third-party misconduct. The precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws. If any such actions are instituted against us, and we are not successful in defending ourselves, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, imprisonment, additional oversight and reporting obligations if we become subject to a corporate integrity agreement or similar agreements to resolve allegations of non-compliance with these laws, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Risks Related to Our Intellectual Property

If we cannot defend our issued patents from third party claims or if our pending patent applications fail to issue, our business could be adversely affected.

To protect our proprietary technology, we rely on patents as well as other intellectual property protections including trade secrets, nondisclosure agreements, and confidentiality provisions. As of June 30, 2021, we are the owner of record of 89 issued patents worldwide. These issued patents cover AcelRx's sufentanil sublingual tablet, medication delivery devices and other platform technology. These issued patents include patents we have listed in the FDA's Orange Book for DSUVIA, and patents expected to provide coverage until 2031. These issued patents also include a European patent covering the DZUVEO device that is expected to provide coverage until at least 2036.

Because sufentanil is not a new chemical entity, its regulatory exclusivity period in the United States is limited to three years under the Hatch-Waxman Act. While the FDA may not approve a 505(b)(2) NDA or abbreviated new drug application, or ANDA, using DSUVIA as its reference listed drug prior to November 2, 2021, we may be subject to certification based on the patents we have listed in the FDA's Orange Book for DSUVIA and engage in litigation against such a 505(b)(2) or ANDA applicant at any time.

In addition, we are pursuing a number of U.S. non-provisional patent applications and foreign national applications directed to DSUVIA and Zalviso. The patent applications that we have filed and have not yet been granted may fail to result in issued patents in the United States or in foreign countries. Even if the patents do successfully issue, third parties may challenge the patents.

Our commercial success will depend in part on successfully defending our current patents against third party challenges and expanding our existing patent portfolio to provide additional layers of patent protection, as well as extending patent protection. There can be no assurance that we will be successful in defending our existing and future patents against third party challenges, or that our pending patent applications will result in additional issued patents.

The patent positions of pharmaceutical companies, including ours, can be highly uncertain and involve complex and evolving legal and factual questions. No consistent policy regarding the breadth of claims allowed in pharmaceutical patents has emerged to date in the United States. Legal developments may preclude or limit the scope of available patent protection.

There is also no assurance that any patents issued to us will not become the subject of adversarial proceedings such as opposition, inter partes review, post-grant review, reissue, supplemental examination, re-examination or other post-issuance proceedings. In addition, there is no assurance that the respective court or agency in such adversarial proceedings would not make unfavorable decisions, such as reducing the scope of a patent of ours or determining that a patent of ours is invalid or unenforceable. There is also no assurance that any patents issued to us will provide us with competitive advantages, will not be challenged by any third parties, or that the patents of others will not prevent the commercialization of products incorporating our technology. Furthermore, there can be no guarantee that others will not independently develop similar products, duplicate any of our products, or design around our patents.

Litigation involving patents, patent applications and other proprietary rights is expensive and time consuming. If we are involved in such litigation, it could cause delays in bringing our products to market and interfere with our business.

Our commercial success depends in part on not infringing patents and proprietary rights of third parties. Although we are not currently aware of litigation or other proceedings or third-party claims of intellectual property infringement related to DSUVIA or Zalviso, the pharmaceutical industry is characterized by extensive litigation regarding patents and other intellectual property rights.

As we enter our target markets, it is possible that competitors or other third parties will claim that our products and/or processes infringe on their intellectual property rights. These third parties may have obtained and may in the future obtain patents covering products or processes that are similar to, or may include compositions or methods that encompass our technology, allowing them to claim that the use of our technologies infringes on these patents.

In a patent infringement claim against us, we may assert, as a defense, that we do not infringe the relevant patent claims, that the patent is invalid or both. The strength of our defenses will depend on the patents asserted, the interpretation of these patents, and our ability to invalidate the asserted patents. However, we could be unsuccessful in advancing non-infringement and invalidity arguments in our defense. In the United States, issued patents enjoy a presumption of validity, and the party challenging the validity of a patent claim must present clear and convincing evidence of invalidity, which is a high burden of proof. Conversely, the patent owner need only prove infringement by a preponderance of the evidence, which is a lower burden of proof.

If we were found by a court to have infringed a valid patent claim, we could be prevented from using the patented technology and be required to pay the owner of the patent for damages for past sales and for the right to license the patented technology for future sales. If we decide to pursue a license to one or more of these patents, we may not be able to obtain a license on commercially reasonable terms, if at all, or the license we obtain may require us to pay substantial royalties or grant cross licenses to our patent rights. For example, if the relevant patent is owned by a competitor, that competitor may choose not to license patent rights to us. If we decide to develop alternative technology, we may not be able to do so in a timely or cost-effective manner, if at all.

In addition, because patent applications can take years to issue and are often afforded confidentiality for some period of time there may currently be pending applications, unknown to us, that later result in issued patents that could cover one or more of our products.

It is possible that we may in the future receive communications from competitors and other companies alleging that we may be infringing their patents, trade secrets or other intellectual property rights, offering licenses to such intellectual property or threatening litigation. In addition to patent infringement claims, third parties may assert copyright, trademark or other proprietary rights against us. We may need to expend considerable resources to counter such claims and may not be successful in our defense. Our business may suffer if a finding of infringement is established.

It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection.

The patent positions of pharmaceutical companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in pharmaceutical patents has emerged to date in the United States. The pharmaceutical patent situation outside the United States is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property.

We cannot predict the breadth of claims that may be allowed or enforced in the patents that may be issued from the applications we currently, or may in the future, own or license from third parties. Claims could be brought regarding the validity of our patents by third parties and regulatory agencies. Further, if any patent license we obtain is deemed invalid and/or unenforceable, it could impact our ability to commercialize or partner our technology.

Competitors or third parties may infringe our patents. We may decide it is necessary to file patent infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, or that the third party's technology does not in fact infringe upon our patents. An adverse determination of any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our related pending patent applications at risk of not issuing. Litigation may fail and, even if successful, may result in substantial costs and be a distraction to our management. We may not be able to prevent misappropriation of our proprietary rights, particularly in countries outside the United States where patent rights may be more difficult to enforce. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential or sensitive information could be compromised by disclosure in the event of litigation. In addition, during the course of litigation there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

The degree of future protection for our proprietary rights is uncertain, and we cannot ensure that:

- we were the first to make the inventions covered by each of our pending patent applications or issued patents;
- our patent applications were filed before the inventions covered by each patent or patent application was published by a third party;
- we were the first to file patent applications for these inventions;
- others will not independently develop similar or alternative technologies or duplicate any of our technologies;
- any patents issued to us or our collaborators will provide a basis for commercially viable products, will provide us with any competitive advantages or will not be challenged by third parties; or
- the patents of others will not have an adverse effect on our business.

If we do not adequately protect our proprietary rights, competitors may be able to use our technologies and erode or negate any competitive advantage we may have, which could materially harm our business, negatively affect our position in the marketplace, limit our ability to commercialize DSUVIA and Zalviso, if approved, and delay or render impossible our achievement of profitability.

We may be unable to adequately prevent disclosure of trade secrets and other proprietary information.

We rely on trade secrets to protect our proprietary know-how and technological advances, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights. Failure to obtain or maintain trade secret protection could enable competitors to use our proprietary information to develop products that compete with our products or cause additional, material adverse effects upon our competitive business position.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and applications will be due to be paid to the United States Patent and Trademark Office and various foreign governmental patent agencies in several stages over the lifetime of the patents and/or applications.

We have systems in place, including use of third-party vendors, to manage payment of periodic maintenance fees, renewal fees, annuity fees and various other patent and application fees. The United States Patent and Trademark Office, or the USPTO, and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. There are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If this occurs, our competitors might be able to enter the market, which would have a material adverse effect on our business.

We may not be able to enforce our intellectual property rights throughout the world.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to life sciences. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit.

Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. Additionally, claims may be brought regarding the validity of our patents by third parties and regulatory agencies in the United States and foreign countries. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain adequate protection for our technology and the enforcement of intellectual property.

We have not yet registered our trademarks in all our potential markets, and failure to secure those registrations could adversely affect our business.

We have registered our ACELRX mark in the United States, Canada, the EU and India. In early 2014, the FDA accepted the Zalviso mark and, in November 2018, the FDA accepted the DSUVIA mark. Although we are not currently aware of any oppositions to or cancellations of our registered trademarks or pending applications, it is possible that one or more of the applications could be subject to opposition or cancellation after the marks are registered. The registrations will be subject to use and maintenance requirements. It is also possible that we have not yet registered all of our trademarks in all of our potential markets, such as securing the registration of DSUVIA in Canada, and that there are names or symbols other than "ACELRX" that may be protectable marks for which we have not sought registration, and failure to secure those registrations could adversely affect our business. Opposition or cancellation proceedings may be filed against our trademarks and our trademarks may not survive such proceedings.

Risks Related to Ownership of Our Common Stock

The market price of our common stock may be highly volatile.*

The trading price of our common stock has experienced significant volatility and is likely to be volatile in the future. For example, the closing price of our common stock ranged between $1.03 and $2.77 during the first six months of 2021, and between $0.76 and $2.07 during the year ended December 31, 2020. Our stock price could be subject to wide fluctuations in response to a variety of factors, including the following:

- failure to successfully commercialize DSUVIA in the United States or to successfully develop and commercialize our product candidates in the United States;
- inability to obtain additional funding needed to conduct our planned business operations;
- inability to satisfactorily comply with FDA regulations concerning the advertising and promotion of DSUVIA, including receiving a close out letter resolving the concerns raised by FDA in the warning letter delivered to us on February 11, 2021;
- the integration and performance of any assets or businesses we acquire;
- our inability to develop and commercialize products and product candidates that we in-license;
- uncertainties regarding the magnitude and duration of impacts we are experiencing due to COVID-19;
- the perception of limited market sizes or pricing for our products;
- further delays in resubmitting the NDA for Zalviso, and any additional adverse developments or perceived adverse developments with respect to the FDA's review of the Zalviso NDA, upon resubmission;
- inability to enter into, or unfavorable terms associated with, a New Arrangement for the commercialization of Zalviso in Europe;
- safety issues;
- adverse results or delays in future clinical trials;
- changes in laws or regulations applicable to our products;
- inability to obtain adequate product supply for our products, or the inability to do so at acceptable prices;
- adverse regulatory decisions;
- changes in the structure of the healthcare payment systems;
- inability to maintain regulatory approvals for DZUVEO and Zalviso in the European Union, including ISO 13485 certification and CE Mark approval for Zalviso;
- introduction of new products, services or technologies by our competitors;
- failure to meet or exceed financial projections we provide to the public;
- failure to meet or exceed the estimates and projections of the investment community;
- decisions by our collaboration partners regarding market access, pricing, and commercialization efforts in countries where they have the right to commercialize our products;
- failure to maintain our existing collaborations or enter into new collaborations;
- the perception of the pharmaceutical industry generally, and of opioid manufacturers more specifically, by the public, legislatures, regulators and the investment community;

- announcements of significant acquisitions, strategic partnerships, joint ventures, or other significant transactions, including disposition transactions, or capital commitments by us or our competitors;
- disputes or other developments relating to employment matters, business development efforts, proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- additions or departures of key management or scientific personnel;
- costs associated with potential governmental investigations, inquiries, regulatory actions or lawsuits that may be brought against us as a result of us being an opioid manufacturer;
- other types of significant lawsuits, including patent, stockholder, securities class action and derivative litigation;
- changes in the market valuations of similar companies;
- sales of our common stock by us or our stockholders in the future; and
- trading volume of our common stock.

In addition, the stock market in general, and The Nasdaq Global Market, or Nasdaq, in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance.

Sales of a substantial number of shares of our common stock in the public market by our stockholders could cause our stock price to fall.

Because we will continue to need additional capital in the future to continue to expand our business and our research and development activities, among other things, we may conduct additional equity offerings. For example, under the universal shelf registration statement filed by us in June 2020 and declared effective by the SEC in July 2020, we may offer and sell any combination of common stock, preferred stock, debt securities and warrants in one or more offerings, up to a cumulative value of $150 million. To date, we have approximately $54.5 million remaining under such universal shelf registration statement. Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. Our management is authorized to grant stock options and other equity-based awards to our employees, directors and consultants under our equity incentive plans. Grants under our equity incentive plans may also cause our stockholders to experience additional dilution, which could cause our stock price to fall. We may also issue shares of our common stock as consideration in mergers, acquisitions and other business development transactions. We are unable to predict the effect that sales may have on the prevailing market price of our common stock. All of our shares of common stock outstanding are eligible for sale in the public market, subject in some cases to the volume limitations and manner of sale requirements of Rule 144 under the Securities Act. Sales of stock by our stockholders could have a material adverse effect on the trading price of our common stock.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.

We have never declared or paid any cash dividends on our capital stock, and we are prohibited from doing so under the terms of the Loan Agreement. Regardless of the restrictions in the Loan Agreement or the terms of any potential future indebtedness, we anticipate that we will retain all available funds and any future earnings to support our operations and finance the growth and development of our business and, therefore, we do not expect to pay cash dividends in the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our Board of Directors and will depend on then-existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects and other factors our Board of Directors may deem relevant.

Provisions in our amended and restated certificate of incorporation and bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders or remove our current management.

Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders and may prevent attempts by our stockholders to replace or remove our current management. These provisions include:

- authorizing the issuance of “blank check” preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;
- limiting the removal of directors by the stockholders;
- a staggered Board of Directors;
- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;

- eliminating the ability of stockholders to call a special meeting of stockholders; and

- establishing advance notice requirements for nominations for election to our Board of Directors or for proposing matters that can be acted upon at stockholder meetings.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our Board of Directors, which is responsible for appointing the members of our management. In addition, we are subject to Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder, unless such transactions are approved by our Board of Directors. This provision could have the effect of delaying or preventing a change of control, whether or not it is desired by or beneficial to our stockholders. Further, other provisions of Delaware law may also discourage, delay or prevent someone from acquiring us or merging with us.

Risks of a General Nature

Litigation may substantially increase our costs and harm our business.*

We have been, are, and may in the future become, party to lawsuits including, without limitation, actions and proceedings in the ordinary course of business relating to our directors, officers, stockholders, intellectual property rights, employment matters and the safety or efficacy of our products, which will cause us to incur legal fees and other costs related thereto, including potential expenses for the reimbursement of legal fees of officers and directors under indemnification obligations. The expense of defending against such litigation may be significant and there can be no assurance that we will be successful in any defense. Further, the amount of time that may be required to resolve such lawsuits is unpredictable, and these actions may divert management’s attention from the day-to-day operations of our business, which could adversely affect our business, results of operations, and cash flows. Our insurance carriers may deny coverage, may be inadequately capitalized to pay on valid claims, or our policy limits may be inadequate to fully satisfy any damage awards or settlements. If this were to happen, the payment of any such awards could have a material adverse effect on our consolidated operations, cash flows and financial position. Additionally, any such claims, whether or not successful, could damage our reputation and business. Litigation is subject to inherent uncertainties, and an adverse result in such matters that may arise from time to time could have a material adverse effect on our business, results of operations, and financial condition. Please see “Part II. Other Information—Item 1. Legal Proceedings” for additional information about pending legal proceedings.

Our involvement in securities-related class action litigation could divert our resources and management's attention and harm our business.*

The stock markets have from time-to-time experienced significant price and volume fluctuations that have affected the market prices for the common stock of pharmaceutical companies. These broad market fluctuations may cause the market price of our common stock to decline. In addition, the market price of our common stock may vary significantly based on AcelRx-specific events, such as receipt of complete response letters, warnings letters, such as the warning letter we received from the FDA on February 11, 2021, negative clinical results, a negative vote or decision by an FDA advisory committee, or other negative feedback from the FDA, EMA, or other regulatory agencies. In the past, securities-related class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies often experience significant stock price volatility in connection with their investigational drug candidate development programs and the FDA's review of their NDAs. Following receipt of the FDA’s warning letter, a securities class action complaint was filed against us and two of our officers on June 8, 2021 in the United States District Court for the Northern District of California. Please see “Part II. Other Information—Item 1. Legal Proceedings” for additional information about this pending legal proceeding. Securities-related class action litigation often is expensive and diverts management's attention and our financial resources, which could harm our business. If AcelRx experiences a decline in its stock price, we could face additional securities class action lawsuits.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

As of December 31, 2020, we had federal net operating loss carryforwards of $264.4 million, of which $114.9 million federal net operating losses generated before January 1, 2018 will begin to expire in 2029. Federal net operating losses of $149.5 million generated after January 1, 2018 will carryforward indefinitely but are subject to the 80% taxable income limitation. As of December 31, 2020, we had state net operating loss carryforwards of $141.5 million, which begin to expire in 2028.

Our ability to use our federal and state net operating losses to offset potential future taxable income and related income taxes that would otherwise be due is dependent upon our generation of future taxable income before the expiration dates of the net operating losses, and we cannot predict with certainty when, or whether, we will generate sufficient taxable income to use all of our net operating losses. Federal net operating losses generated prior to 2018 will continue to be governed by the net operating loss tax rules as they existed prior to the adoption of the Tax Cuts and Jobs Act of 2017, or Tax Act, which means that generally they will expire 20 years after they were generated if not used prior thereto. Many states have similar laws. Accordingly, our federal and state net operating losses could expire unused and be unavailable to offset future income tax liabilities. Under the newly enacted Tax Act as modified by CARES Act, federal net operating losses incurred in tax years beginning after December 31, 2017 and before January 1, 2021 may be carried back to each of the five tax years preceding such loss, and federal net operating losses arising in tax years beginning after December 31, 2020 may not be carried back. Moreover, federal net operating losses generated in tax years ending after December 31, 2017 may be carried forward indefinitely, but the deductibility of such federal net operating losses is limited to 80% of current year taxable income for tax years beginning after December 31, 2020.

In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change," generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes (such as research tax credits) to offset its post-change income may be limited. The completion of the July 2013 public equity offering, together with our public equity offering in December 2012, our initial public offering, private placements and other transactions that have occurred, have triggered such an ownership change. In addition, since we will need to raise substantial additional funding to finance our operations, we may undergo further ownership changes in the future. In the future, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards to offset United States federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us.

Our effective tax rate may fluctuate, and we may incur obligations in tax jurisdictions in excess of accrued amounts.

We are subject to taxation in numerous U.S. states and territories. As a result, our effective tax rate is derived from a combination of applicable tax rates in the various places that we operate. In preparing our financial statements, we estimate the amount of tax that will become payable in each of such places. Nevertheless, our effective tax rate may be different than experienced in the past due to numerous factors, including passage of the newly enacted federal income tax law, changes in the mix of our profitability from state to state, the results of examinations and audits of our tax filings, our inability to secure or sustain acceptable agreements with tax authorities, changes in accounting for income taxes and changes in tax laws. Any of these factors could cause us to experience an effective tax rate significantly different from previous periods or our current expectations and may result in tax obligations in excess of amounts accrued in our financial statements.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit Number	Exhibit Description	Incorporation By Reference			
		Form	SEC File No.	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation of the Registrant.	8-K	001-35068	3.1	02/18/2011
3.2	Certificate of Amendment of Amended and Restated Certificate of Incorporation of the Registrant.	8-K	001-35068	3.1	6/25/2019
3.3	Amended and Restated Bylaws of the Registrant.	S-1	333-170594	3.4	01/07/2011
10.1§#	Commercial Supply Agreement, effective March 31, 2021 by and between Catalent Pharma Solutions, LLC and the Registrant.				
10.2+	Amended and Restated 2020 Equity Incentive Plan	8-K	001-35068	10.1	6/17/2021
31.1	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.				
31.2	Certification of Principal Financial and Accounting Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.				
32.1	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*				
101.INS	Inline XBRL Instance Document- the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.				
101.SCH	Inline XBRL Taxonomy Schema Document.				
101.CAL	Inline XBRL Taxonomy Calculation Linkbase Document.				
101.DEF	Inline XBRL Taxonomy Definition Linkbase Document.				
101.LAB	Inline XBRL Taxonomy Label Linkbase Document.				
101.PRE	Inline XBRL Taxonomy Presentation Linkbase Document.				
104	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 101.INS, 101.SCH, 101.CAL, 101.DEF, 101.LAB, and 101.PRE).				

§ Schedules omitted pursuant to Item 601(a)(5) of Regulation S-K. The Registrant agrees to furnish supplementally a copy of any omitted schedule upon request by the SEC.

+ Indicates management contract or compensatory plan.

Material in the exhibit marked with an "[***]" has been omitted because it is confidential, not material, and would be competitively harmful if publicly disclosed.

* The certifications attached as Exhibit 32.1 accompany this Quarterly Report on Form 10-Q pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed "filed" by the Registrant for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Date: August 16, 2021

AcelRx Pharmaceuticals, Inc.
(Registrant)

/s/ Raffi Asadorian

Raffi Asadorian
Chief Financial Officer
(Duly Authorized and Principal Financial and Accounting Officer)

Exhibit 10.1

[***] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE THE INFORMATION (I) IS CONFIDENTIAL, (II) IS NOT MATERIAL, AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

COMMERCIAL SUPPLY AGREEMENT

DSUVIA® (sufentanil)

This Commercial Supply Agreement ("**Agreement**") is made as of this 31st day of March, 2021 (the "**Effective Date**"), by and between AcelRx Pharmaceuticals, Inc., a Delaware corporation, with a place of business at 351 Galveston Drive, Redwood City, California 94063 ("**Client**"), and Catalent Pharma Solutions, LLC, a Delaware limited liability company, with a place of business at 14 Schoolhouse Road, Somerset, New Jersey 08873, USA ("**Catalent**"). Client and Catalent are each a "Party" and are collectively referred to herein as "Parties".

RECITALS

A. Client is a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for use in medically supervised setting;

B. Catalent is a leading provider of advanced technologies, and development, manufacturing and packaging services for pharmaceutical, biotechnology and consumer healthcare companies;

C. Client desires to engage Catalent to provide certain services to Client in connection with the processing and packaging of Client Product (as defined below) intended for commercialization, and Catalent desires to provide such services, all pursuant to the terms and conditions set forth in this Agreement.

THEREFORE, in consideration of the mutual covenants, terms and conditions set forth below, the Parties agree as follows:

ARTICLE 1
DEFINITIONS

The following terms have the following meanings in this Agreement:

1.1 "**Acknowledgement**" has the meaning set forth in Section 4.2(B).

1.2 "**Affiliate(s)**" means with respect to any individual, corporation, partnership, limited liability company, association, trust, unincorporated entity, or other legal entity (each a "**Person**"), any other Person that directly, or indirectly through one or more intermediaries, controls, is controlled by, or is under common control with such Person. For the purposes of this definition, "**control**" (including, with correlative meanings, "controlled by" and "under common control with") shall mean possession, directly or indirectly, of the power to direct the management and policies of a Person, whether through the ownership of 50% or more of the voting interests of such Person, through contract, or otherwise.

1.3 "**Agreement**" has the meaning set forth in the introductory paragraph and includes all its attachments and other appendices (all of which are incorporated herein by reference) and any amendments to any of the foregoing made as provided herein or therein.

1.4 **"Annual Fee"** has the meaning set forth in Section 7.1.

1.5 "**Applicable Laws**" means, with respect to Client, all laws, ordinances, rules and regulations, currently in effect or enacted or promulgated during the Term, and as amended from time to time, of each jurisdiction in which Client-supplied Materials, Client Product or Drug Product is produced, marketed, distributed, used or sold; and with respect to Catalent, all laws, ordinances, rules and regulations, currently in effect or enacted or promulgated during the Term, and as amended from time to time, of the jurisdiction in which Catalent Processes Client-supplied Materials or produced Client Product, including cGMP.

1.6 **"Background IP"** has the meaning set forth in Article 11.

1.7 "**Bailee Waiver Letter**" means a wavier letter executed by Catalent in favor of collateral agents under any secured debt of Client and substantially in the form attached to this Agreement as Attachment F.

1.8 "**Batch**" means a defined quantity of a single production run of Client Product that has been or is being Processed in accordance with the Specifications and the Quality Agreement.

1.9 "**Batch Record**" means the written record of the materials and processing steps to Process the Raw Materials and Client-supplied Materials to produce Client Product.

1.10 "**Catalent**" has the meaning set forth in the introductory paragraph, or any successor or permitted assign. Catalent shall have the right to cause any of its Affiliates to perform any of its obligations hereunder in accordance with this Agreement, and Client shall accept such performance as if it were performance by Catalent.

1.11 "**Catalent Defective Processing**" has the meaning set forth in Section 5.2.

1.12 "**Catalent Indemnitees**" has the meaning set forth in Section 13.2.

1.13 **"Catalent Inventions**" has the meaning set forth in Article 11.

1.14 "**Certificate of Compliance**" means a statement that a particular Batch of Client Product was Processed, manufactured, packaged/labelled and tested (as applicable) in accordance with cGMP and the Batch Record, identifies the master Batch Record documents and lists any deviation reports and investigations associated with the Batch of Client Product.

1.15 "**cGMP**" means current Good Manufacturing Practices promulgated by the Regulatory Authorities in the jurisdictions included in Applicable Laws (as applicable to Client and Catalent respectively). In the United States, this includes 21 C.F.R. Parts 210 and 211, as amended; and in the European Union, this includes 2003/94/EEC Directive (as supplemented by Volume 4 of EudraLex published by the European Commission), as amended, if and as implemented in the relevant constituent country.

1.16 "**Client**" has the meaning set forth in the introductory paragraph, or any successor or permitted assign.

1.17 "**Client Equipment**" means all the equipment purchased and owned by Client for use by Catalent, and all the equipment purchased by Catalent for Client and invoiced to or purchased by Client. Client shall hold title for all such equipment, including the equipment listed in or added to Attachment D. Attachment D shall be amended from time to time to reflect any additional equipment purchased by Client.

1.18 "**Client Indemnitees**" has the meaning set forth in Section 13.1.

1.19 "**Client Inventions**" has the meaning set forth in Article 11.

1.20 **"Client Product"** means a packaged single dose applicator ("**SDA**") containing the Drug Product, as more fully and specifically described in the Specifications and Quality Agreement.

1.21 **"Client Proprietary Process"** means Client's proprietary packaging process for exclusively packaging Drug Product with Client Equipment to produce Client Product.

1.22 "**Client-supplied Materials**" means any materials to be supplied by or on behalf of Client to Catalent for Processing, including but not limited to Drug Product, Raw Materials, placebo, devices, applicators, reference standards, and other materials.

1.23 "**Commencement Date**" means the first date upon which the FDA approves Catalent as a manufacturer of the Client Product in the Territory.

1.24 "**Confidential Information**" has the meaning set forth in Section 10.1.

1.25 "**Client Equipment Consumable Parts**" means non-repairable parts that are used-up or worn out and have to be replaced regularly for the Client Equipment.

1.26 "**Contract Year**" means, for each Client Product, each consecutive 12 month period beginning on the Commencement Date or anniversary thereof, as applicable.

1.27 "**Defective Product**" has the meaning set forth in Section 5.2.

1.28 "**Discloser**" has the meaning set forth in Section 10.1.

1.29 "**Drug Product**" means the sublingual tablet 30 mcg sufentanil dosage form contained in the pharmaceutical product, DSUVIA® (sufentanil), as further described in the Specifications that has been released by Client and provided to Catalent, along with a certificate of analysis and as provided in the Quality Agreement.

1.30 "**Effective Date**" has the meaning set forth in the introductory paragraph.

1.31 "**Equipment Instructions**" means the Client Equipment manufacturer's instructions and requirements.

1.32 "**Equipment Delivery Date**" means the date on which Client delivers to the Facility the Client Equipment manufactured by Harro Höfliger on behalf of Client and included in Attachment D.

1.33 "**Exception Notice**" has the meaning set forth in Section 5.2.

1.34 "**Facility**" means Catalent's facility located in 10245 Hickman Mills Drive, Kansas City, MO 64137; or such other facility as agreed by the Parties in writing.

1.35 "**Facility Fee**" has the meaning set forth in Section 7.1.

1.36 "**Firm Commitment**" has the meaning set forth in Section 4.1.

1.37 **"FDA"** means the U.S. Food and Drug Administration, an agency within the U.S. Department of Health and Human Services.

1.38 "**Invention**" has the meaning set forth in Article 11.

1.39 "**Latent Defect**" means a defect of the Batch attributable solely to [***].

1.40 "**Lien**" means any legal charge, debenture, mortgage, deed of trust, security interest, pledge, lien, assignment or other encumbrance of any kind whether imposed by any agreement, contract, lease, sublease, license, sublicense, obligation, instrument or undertaking, Applicable Law or otherwise, whether fixed or floating, or conferring priority of payment.

1.41 "**Losses**" has the meaning set forth in Section 13.1.

1.42 "**Party**" means Catalent or Client, as applicable. "**Parties**" means Catalent and Client.

1.43 "**PPQ**" has the meaning in the SRA as follows: means the process performance qualification for the Processing of Client Product as provided in the Specifications.

1.44 "**Process**" or "**Processing**" or "**Processed**" means the packaging of Client-supplied Materials and Raw Materials to produce Client Product by Catalent, in accordance with the Specifications, the Quality Agreement, and under the terms of this Agreement.

1.45 "**Processing Date**" means the day on which the first step of physical Processing is scheduled to occur, as identified in an Acknowledgement or as otherwise communicated by Catalent to Client in writing.

1.46 "**Product Maintenance Services**" has the meaning set forth in Section 2.10.

1.47 "**Purchase Order**" has the meaning set forth in Section 4.2.

1.48 "**Quality Agreement**" means the quality agreement executed by the Parties and attached to this Agreement as Attachment E, as may be amended from time to time.

1.49 "**Raw Materials**" means all raw materials, supplies, labels, translations, components and packaging necessary to Process and ship Client Product in accordance with the Specifications, and which are supplied by Catalent on behalf of Client at Client's cost.

1.50 "**Recall**" has the meaning set forth in Section 9.5.

1.51 "**Recipient**" has the meaning set forth in Section 10.1.

1.52 "**Regulatory Approval**" means the approval of Client's supplemental application for the Processing of Client-supplied Materials by Catalent at the Facility that is necessary or advisable in connection with the manufacture, testing, use, storage, exportation, importation, transport, promotion, marketing, distribution or sale of Client Product in the Territory.

1.53 "**Regulatory Authority**" means the international, federal, state or local governmental or regulatory bodies, agencies, departments, bureaus, courts or other entities responsible for (A) the regulation (including pricing) of any aspect of pharmaceutical or medicinal products intended for human use, including the United States Drug Enforcement Agency or any other international, federal, state or local regulatory bodies, agencies, departments, bureaus, courts or other entities responsible for the regulation of drugs, or (B) health, safety or environmental matters generally. In the United States, this includes the United States Food and Drug Administration; and in the European Union, this includes the European Medicines Agency.

1.54 "**Representatives**" of an entity means such entity's duly-authorized officers, directors, employees, agents, accountants, attorneys or other professional advisors.

1.55 "**Review Period**" has the meaning set forth in Section 5.2.

1.56 "**Rolling Forecast**" has the meaning set forth in Section 4.1.

1.57 "**Site**" has the meaning in the SRA as follows: means 10245 Hickman Mills Drive, Kansas City, MO 64137

1.58 "**Serialization**" means the serialization of Client Product in accordance with the Quality Agreement and Applicable Laws in the Territory.

1.59 "**Client Equipment Spare Parts**" means interchangeable parts of the Client Equipment that are kept in inventory and are used to replace parts that have failed.

1.60 "**SAT**" has the meaning in the SRA, site acceptance testing of Client Equipment.

1.61 "**Specifications**" means the specifications as agreed to by the Parties in writing which define the process for Processing Client Product, as well as any specifications for Client-supplied Materials, Raw Materials and for Drug Product, and which, once established, are set forth in the Quality Agreement and in Attachment B, as Attachment B and/or the foregoing may be modified from time to time in accordance with Article 8.

1.62 "**SRA**" or "**Site Readiness Agreement**" means the Site Readiness Agreement between the Parties with an effective date of August 15, 2019, as amended by Amendment One on September 24, 2020.

1.63 "**Term**" has the meaning set forth in Section 16.1.

1.64 "**Territory**" means the United States, and any other country that the parties agree in writing to add to this definition of Territory in an amendment to this Agreement, but excluding any countries that are targeted by the comprehensive sanctions, restrictions or embargoes administered by the United Nations, European Union, United Kingdom, or the United States. Catalent shall not be obliged to Process Client Product for sale in any of such countries if it is prevented from doing so, or would be required to obtain or apply for special permission to do so, due to any restrictions (such as embargoes) imposed on it by any governmental authorities, including without limitation, those imposed by the U.S. Office of Foreign Assets Control.

1.65 "**Unit**" has the meaning set forth in Attachment C.

1.66 "**Unit Pricing**" has the meaning set forth in Section 7.1 (B).

1.67 "**Vendor**" has the meaning set forth in Section 3.2.

ARTICLE 2
CLIENT EQUIPMENT, FACILITY, VALIDATION, PROCESSING & RELATED SERVICES

2.1 Client Equipment. Client Equipment will be used by Catalent solely to perform services for Client and as expressly permitted in accordance with this Article 2. In the event that any part of the Client Equipment becomes unfit for use, or the efficiency of operation or performance of any part of the Client Equipment is diminished, excluding diminishment due to normal wear and tear, Client, at its own cost and expense, shall promptly replace or cause to be replaced such affected part of the Client Equipment with one or more replacement parts (or in an extreme situation and where absolutely necessary, replace the entire affected Client Equipment). Client shall ensure that such replacement part(s) (or the entire replacement of the Client Equipment, if applicable) results in the Client Equipment being fit for use, or returned to a level of operation and performance that existed prior to such replacement due to diminishment (but excluding normal wear and tear).

2.2 Title to Client Equipment; Risk of Loss Regarding Client Equipment.

A. Title to Client Equipment. Client shall own sole title to all Client Equipment at all times. Catalent acknowledges and agrees that it does not have, and will not have, any ownership or property interest in the Client Equipment at any time. At Client's request, Catalent shall mark, or will allow Client to mark, the Client Equipment with appropriate tags, labels or lettering as being the property of Client provided that such marking does not interfere with Processing. Catalent shall maintain those markings and any similar markings that Client placed or had placed on the Client Equipment before or after delivering the Client Equipment to Catalent. Catalent shall not knowingly represent to any Regulatory Authority or Third Party, and shall not represent in any public disclosure, including any financial statement or tax return, that it has any property interest in the Client Equipment, or make any other public or non-public statement or representation that is inconsistent with Client's retention of all right, title, and interest in and to the Client Equipment, as provided herein.

B. Risk of Loss Regarding Client Equipment. Provided that the Client Equipment is possessed, handled, used and maintained in accordance with this Agreement, the Equipment Instructions and the Quality Agreement, then as between Client and Catalent, Client shall bear risk of loss or damage to the Client Equipment, including normal wear and tear.

2.3 No Liens by Catalent in Relation to Client Equipment. Catalent shall not do or permit or cause anything to be done whereby Client's rights in and title to the Client Equipment are prejudiced. Catalent has no right, title or interest in the Client Equipment against which any Lien may be granted. Accordingly, Catalent shall keep the Client Equipment free of all Liens that are filed by Catalent or against Catalent, and Catalent shall promptly take any action necessary to discharge any such Client Equipment-specific Lien that is filed by Catalent or against Catalent that exists at any time as a result of Catalent's breach of this Article 2, at Catalent's own cost and expense.

2.4 Bailee Waiver. As bailee of the Client Equipment (to the extent that it is part of Client's collateral for Client's secured debt), Catalent will execute a Bailee Waiver Letter, in substantially the form provided in Attachment F, within [***] business days of the Client's request for such Bailee Waiver Letter

2.5 Catalent Obligations Regarding Client Equipment.

A. Catalent shall safekeep the Client Equipment, will perform maintenance of the Client Equipment, and shall use Client Equipment only in accordance with the Equipment Instructions at Client's cost. Subject at all times to applicable health and safety requirements, when Processing the Client Product, Catalent shall operate the Client Equipment as provided in the Equipment Instructions.

B. Catalent shall use the Client Equipment in compliance with Applicable Laws, Equipment Instructions and the Quality Agreement.

C. Catalent shall maintain the Client Equipment as Confidential Information of the Client, including not permitting Third Parties to access the Client Equipment, except as Client Confidential Information is permitted to be disclosed, as provided in Article 10.

2.6 Location, Use, Maintenance and Repair of Client Equipment.

A. No item of Client Equipment shall be moved from the Facility or relocated within the Facility without the prior written agreement of the Parties, not to be unreasonably withheld or delayed.

B. Except as provided in this Article 2, Catalent shall not use the Client Equipment for any purpose other than in accordance with this Agreement without Client's prior written consent.

C. Catalent shall (i) maintain the Client Equipment in good, safe and efficient operating repair, appearance and condition in accordance with Equipment Instructions and the Quality Agreement; (ii) keep all components of the Client Equipment properly calibrated and aligned at Clients' cost; (iii) make all required adjustments and perform replacements to the Client Equipment, at Client's written direction and cost; and (iv) obtain and install any upgrades for the Client Equipment as directed by the Client, or that are required for the purpose of maintaining any standard maintenance contract and are related to the use of the Client Equipment by Catalent, as agreed to in writing by Catalent and Client and at Client's cost. All such maintenance shall be performed by Catalent, with assistance from the Client Equipment manufacturer, as necessary, at Client's cost. Client shall be responsible for the cost of all parts, materials, contracted maintenance services and Client Equipment manufacturer technical support and labor required for Client Equipment maintenance. Catalent shall not permit the Client Equipment to be used or maintained, in any manner or condition, or for any purpose, not provided in the Equipment Instructions, Applicable Laws, the Quality Agreement or otherwise under this Agreement. For any and all costs paid by Catalent in connection with maintenance, alignment, adjustment, upgrades repair or calibration of the Client Equipment or otherwise as described in this Article 2, Catalent shall provide to Client documentation that supports such costs incurred by Catalent and Client shall bear the cost thereof.

D. In the event that the Client Equipment or any portion of it shall become damaged or is defective, then Catalent, at Client's cost and expense in accordance with this Article 2, shall place the damaged portions in good repair, condition and working order, or with Client's written approval, replace same with like property having the same operating capabilities at least equal to, the damaged portions of the Client Equipment as soon as possible. All such repairs or replacements shall be performed by representatives of the Client Equipment manufacturer or, with Client's written approval, those of substantially equal skill or knowledge and engaged by Catalent for repairing the Client Equipment, at Client's cost.

E. Catalent shall not make any alteration, addition, modification, enhancement or improvement to the Client Equipment without Client's prior written consent.

F. Client shall identify a list of critical Client Equipment Spare Parts to be maintained in inventory at Catalent, at Client's cost. Catalent will notify Client in writing when Client Equipment Spare Parts have been used and Client will arrange for Client Equipment Spare Parts replacements.

G. Client shall identify a list of Client Equipment Consumable Parts to be maintained in inventory at Catalent. Catalent will manage inventory of Client Equipment Consumable Parts and will arrange for Client Equipment Consumable Part replacements, at Client's cost.

2.7 Facility. Catalent shall bear all (i) risk of loss or damage to the Facility generally; and (ii) costs arising from use, maintenance and repair of the Facility, including any loss or damage to the Facility caused by improper installation and use of the Client Equipment at the Facility. Catalent shall be responsible for the maintaining, at its sole expense, the cost of property insurance on the Facility. Catalent shall not bear the risk of loss or damage or damage to the Facility due to Client Equipment failure or defective Client Equipment.

2.8 Other Services This Agreement shall not cover or extend to any additional services by Catalent to Client, including but not limited to Client Product validation services, Client Equipment re-validation services, Client Product re-validation services, or any services necessary to support the validation or re-validation portion of Client's submissions for Regulatory Approvals or PPQ. Any additional services are each at Client's cost and expense and subject to a separate definitive agreement between the Parties.

2.9 Supply and Purchase of Product. Catalent shall Process Client-supplied Materials, including Drug Product and Raw Materials, in accordance with the Specifications, Applicable Laws, Unit Pricing and other fees as expressly set forth in the terms and conditions of this Agreement.

2.10 Product Maintenance Services. Client will receive the following product maintenance services (the "**Product Maintenance Services**"): one annual audit (as further described in Section 9.4); regulatory inspections (as further described in Section 9.3); one annual product review (within the meaning of 21 CFR § 211.180) per Drug Product and Client Product; serialization per Drug Product and Client Product packaging configuration; drug master file updates for the Territory, if applicable; access to document library over and above the Quality Agreement, including additional copies of Batch Records, Batch paperwork or other Batch documentation; assistance in preparing Regulatory Approvals; monthly inventory reports, annual inventory support, Drug Product and Client Product documents and sample storage relating to cGMP requirements; vendor re-qualification; maintenance, updates and storage of master batch records and audit reports; and tooling and filter bag maintenance, as applicable. For avoidance of doubt, the following services and items are not included in Product Maintenance Services: technology transfer; analytical work; stability, process rework, PPQ, maintenance and repair of Client Equipment and Validation Services.

ARTICLE 3
MATERIALS

3.1 Client-supplied Materials.

A. Client shall supply to Catalent for Processing, at Client's cost, all Client-supplied Materials, in quantities sufficient to meet Client's requirements for Client Product as set forth in the Specifications with respect to such Client Product. Client shall deliver such Client-supplied Materials and associated certificates of analysis to the Facility no later than [***] days, or as otherwise agreed to in writing by the Parties, before the Processing Date. Client shall be responsible at its expense for securing any necessary DEA, export license or import permit, similar clearances, permits or certifications required by Regulatory Authorities in respect of such Client-supplied Materials. Catalent shall use such items solely for Processing. Prior to delivery of any such Client-supplied Materials or Drug Product by Client to Catalent, Client shall provide to Catalent a copy of all associated material safety data sheets, safe handling instructions and health and environmental information and any Regulatory Authority certifications or authorizations that may be required under Applicable Laws relating to the Client-supplied Materials and Drug Product, and shall promptly provide any updates thereto received by Client. If Drug Product is a List 1 chemical or controlled substance under Applicable Laws, including Drug Enforcement Agency regulations, then each Party will handle such Drug Product, Processing thereof and Client Product in accordance with the material safety data sheets and all requirements set forth in the Specifications, the Quality Agreement and Applicable Laws. Cost for storage of Client-supplied Materials, Drug Product and Client Product is provided in Attachment C.

B. Following receipt of Client-supplied Materials, including Drug Product, Catalent shall inspect such items to verify their identity. Unless otherwise expressly required by the Specifications, Catalent shall have no obligation to test such items to confirm that they meet the associated specifications or certificate of analysis or otherwise; but in the event that Catalent detects a nonconformity with the Specifications, Catalent shall give Client prompt written notice of such nonconformity. Catalent shall not be liable for any defects (including latent defects) in Client-supplied Materials, including Drug Product, that are attributable to defective Client-supplied Materials (including defective Drug Product), unless Catalent failed to properly perform the foregoing obligations. Catalent shall follow Client's reasonable written instructions in respect of return or disposal of defective Client-supplied Materials and Drug Product, at Client's cost.

C. Client shall retain title to Client-supplied Materials at all times and shall bear the risk of loss thereof, unless subject to Article 14.

3.2 Raw Materials.

A. Catalent shall on behalf of Client at Client's expense be responsible for procuring, inspecting and releasing adequate Raw Materials as necessary to meet the Firm Commitment, unless otherwise agreed to by the Parties in writing. Catalent shall not be liable for any delay in delivery of Client Product if (i) Catalent is unable to obtain, in a timely manner, using commercially reasonable efforts, a particular Raw Material necessary for Processing and (ii) Catalent placed orders for such Raw Materials promptly following receipt of Client's Firm Commitment. Client acknowledges that Catalent will rely upon the Rolling Forecast to purchase long lead time materials needed for Processing in accordance with the Firm Commitment. In the event that any Raw Material becomes subject to purchase lead time beyond the Firm Commitment time frame, the Parties will negotiate in good faith an appropriate amendment to this Agreement, including Section 4.2.

B. In certain instances, Client may require a specific supplier, manufacturer or vendor ("**Vendor**") to be used for supply of a Raw Material. In such an event, (i) such Vendor will be identified in the Specifications and (ii) the Raw Materials from such Vendor shall be deemed Client-supplied Materials for purposes of this Agreement. If the cost of the Raw Material from any such Vendor is greater than Catalent's costs for the same raw material of equal quality and quantity from other vendors, Catalent shall add the difference between Catalent's cost of the Raw Material and the Vendor's cost of the Raw Material to the Unit Pricing. Client will be responsible for all costs associated with qualification of any such Vendor who has not been previously qualified by Catalent.

C. In the event of (i) a Specification change for any reason, or (ii) obsolescence of any Raw Materials, Client shall bear the cost of any unused Raw Materials (including but not limited to packaging and labels), so long as Catalent purchased such Raw Materials in accordance with this Agreement, and in quantities consistent with Client's Rolling Forecast and most recent Firm Commitment and the vendor's minimum purchase obligations. All such unused Raw Materials paid for by Client shall be delivered to Client.

3.3 Artwork and Labeling. Client shall provide or approve in writing, prior to the procurement of all applicable Raw Materials on behalf of Client and invoiced to Client, all Raw Materials Specifications including but not limited to all artwork, advertising, inserts and labeling information necessary for Processing. Such artwork, advertising, inserts and labeling information is and shall remain the exclusive property of Client, and Client shall be solely responsible for the content thereof. Such artwork, advertising, inserts and labeling information or any reproduction thereof may not be used by Catalent in any manner other than performing its obligations hereunder.

ARTICLE 4
PURCHASE ORDERS & FORECASTS

4.1 Forecast. On or before the [***] day of each calendar month, beginning at least [***] months prior to the anticipated Commencement Date, Client shall furnish to Catalent a written [***] rolling forecast of the quantities of Client Product that Client intends to order from Catalent during such [***] period ("**Rolling Forecast**"); *provided*, that the quantities forecasted to be purchased shall not exceed the capacity of the Client Equipment and Catalent's manufacturing capacity for Processing of the Client Product. The first [***] months of such Rolling Forecast shall constitute a binding order for the quantities of Client Product specified therein ("**Firm Commitment**") and the following [***] months of the Rolling Forecast shall be non-binding, good faith estimates.

4.2 Purchase Orders.

A. From time to time as provided in this Section 4.2(A), Client shall submit to Catalent a binding, non-cancelable purchase order for Client Product specifying the number of Batches to be Processed, the Batch size (to the extent the Specifications permit Batches of different sizes) and the requested delivery date for each Batch and reference to this Agreement ("**Purchase Order**"). Concurrently with the submission of each Rolling Forecast on a monthly basis, Client shall submit a Purchase Order for the Firm Commitment. Purchase Orders for quantities of Client Product in excess of [***]% of the Firm Commitment shall be submitted by Client at least [***] days in advance of the delivery date requested for such excess quantities of Client Product that are in the Purchase Order.

B. Within [***] business days following receipt of a Purchase Order, Catalent shall issue a written acknowledgement ("**Acknowledgement**") that it accepts or rejects the Batch size and delivery date of such Purchase Order only. Any other information in the Purchase Order such as Unit Pricing or other pricing and information will be for information only. The Unit Pricing is that pricing in effect as of the date of the Purchase Order in accordance with this Agreement for delivery within one year of the date of the Purchase Order. In the event the delivery date of the Purchase Order is one year or greater, then the Unit Pricing shall be in effect as of the date of delivery in accordance with this Agreement. Catalent may accept, reject, or modify any Purchase Order in excess of the Firm Commitment. Each acceptance Acknowledgement shall either confirm the delivery date(s) set forth in the Purchase Order or set forth a reasonable alternative delivery date. Acknowledgement and fulfillment of any Purchase Order quantities in excess of [***]% of the Firm Commitment, or otherwise in any Purchase Order not given in accordance with this Agreement, will only be acknowledged by mutual written agreement of the Parties.

C. Notwithstanding anything to the contrary in Section 4.2(B), Catalent shall use commercially reasonable efforts to supply Client with quantities of Client Product which are up to [***]% in excess of the quantities specified in the Firm Commitment, subject to Catalent's other supply commitments and manufacturing, packaging and equipment capacity and the capacity of the Client Equipment and Catalent's Processing capacity for the Client Product.

D. In the event of a conflict between the terms of any Purchase Order or Acknowledgement and this Agreement, the terms of this Agreement shall control.

4.3 Catalent's Cancellation or Suspension of Purchase Orders. Notwithstanding anything to the contrary in Section 4.4, Catalent reserves the right to cancel or suspend all, or any part of, a Purchase Order upon advance written notice to Client. For a cancellation by Catalent, Catalent shall have no further obligations of liability with respect to such Purchase Order, if (A) Client refuses or fails to timely supply conforming and required Client-supplied Materials in accordance with Section 3.1, (B) Catalent does not receive the required allocation of Drug Enforcement Agency procurement quota for the active pharmaceutical ingredient present in the Drug Product, or (C) the Purchase Order exceeds the Client Equipment capacity. Any cancellation or suspension of any part of such Purchase Order pursuant to (A), (B) or (C) of the prior sentence in this Section 4.3, shall not constitute a breach of this Agreement by Catalent nor shall it absolve Client of its obligations in respect of the Annual Fee.

4.4 Client's Modification or Cancellation of Purchase Orders. Client may modify the delivery date or quantity of Client Product in a Purchase Order only by submitting a written change order to Catalent at least [***] days in advance of the earliest Processing Date covered by such change order. Such change order shall be effective and binding against Catalent only upon the written approval of Catalent, and notwithstanding the foregoing, Client shall remain responsible for the Firm Commitment.

4.5 Failure to Satisfy Firm Commitment. Notwithstanding any amounts due to Catalent under Section 4.4 or Section 4.1, if Client fails to place Purchase Orders sufficient to satisfy the Firm Commitment in accordance with Section 4.1, Client shall pay to Catalent in accordance with Article 7 the Unit Pricing for the Units in the Purchase Orders and all additional Units that would have been Processed if Client had placed Purchase Orders sufficient to satisfy the Firm Commitment. In the event Raw Materials have been sourced by Catalent for the Firm Commitment and Client does not place Purchase Orders sufficient to satisfy the Firm Commitment in accordance with Section 4.1, then Catalent will provide a credit toward the Raw Materials pricing in Exhibit C for only the next Purchase Order, provided the Raw Materials are available for use in accordance with the Quality Agreement for the next Firm Commitment less administrative, storage and expired Raw Materials. This credit shall only be extended one time per Contract Year.

4.6 Unplanned Delay or Elimination of Processing. Catalent shall use commercially reasonable efforts to supply in accordance with the Purchase Orders, subject to the terms and conditions of this Agreement. Catalent shall provide Client with as much advance written notice as practicable promptly after Catalent determines that any Processing will be delayed for any reason.

4.7 Observation of Processing. In addition to Client's audit right pursuant to Section 9.4, Client may send up to [***] representatives to the Facility to observe Processing for a maximum of [***] days per Contract Year, during regular business hours (unless otherwise agreed to by Catalent in writing), upon at least [***] business days prior written notice from the Client. Such representatives shall abide by all Catalent safety rules and other applicable employee policies and procedures, and Client shall be responsible for such compliance by Client's representatives. Client shall indemnify and hold harmless Catalent for any action, omission or other activity of such Client representatives while on Catalent's premises. Client representatives that are not employees of Client, shall be required to sign Catalent's standard visitor confidentiality agreement prior to being allowed access to the Facility.

4.8 Transfer. In the event of a Transfer in accordance with Section 16.1 or an assignment pursuant to Section 18.7, respectively, to a third party, then the third party will assume all Client responsibilities and obligations per this Agreement, including future Annual Fee payments at the existing quarterly rate as of the Transfer Date. Effective on the Transfer Date, the third party shall assume all new costs, ownership and responsibilities for the Agreement. Client shall be responsible for all obligations under this Agreement before the Transfer Date, including but not limited to all Purchase Orders, invoices, payments accrued before the Transfer Date and all terms and conditions that survive this Agreement as provided in Section 16.5. Any costs of transferring the Agreement and Inventory shall be borne by Client.

ARTICLE 5
RELEASE, DEFECTIVE PRODUCT AND ANALYTICAL TESTING

5.1 Batch Records and Data; Release. Unless otherwise agreed to by the Parties during their ordinary course of dealings or unless otherwise included in the Quality Agreement, after Catalent completes Processing of a Batch, Catalent shall provide Client with copies of Batch Records and a Certificate of Compliance prepared in accordance with the Quality Agreement. Client shall be responsible for final release of Client Product including testing, at its cost to the market.

5.2 Testing; Rejection.

A. Following Catalent's release of a Batch, Client or Client's designee may test samples of such Batch to confirm that the Specifications have been met. A Batch shall be deemed accepted by Client and Client shall have no right to reject such Batch and such Batch shall be deemed accepted by Client , unless, within [***] days after Catalent's release of a Batch ("**Review Period**"), Client or its designee notifies Catalent in writing (an "**Exception Notice**") that such Batch does not meet the warranty set forth in Section 12.1 ("**Defective Product**") and provides a sample of the alleged Defective Product. However, if Client thereafter discovers a Latent Defect (for example, of the printing of the Package Insert or Carton, or Serialization of the Batch), it shall notify Catalent in writing with an Exception Notice of such Latent Defect within [***] of the discovery of the Latent Defect, but in no event later than [***] after tender of delivery of such Batch, and upon delivery of such Exception Notice the Batch alleged to have a Latent Defect will be hereafter referred to as Defective Product.

B. Upon timely receipt of an Exception Notice from Client, Catalent shall conduct an appropriate investigation to determine whether or not it agrees with Client that such Batch of Client Product is Defective Product and to determine the cause of any nonconformity. If Catalent agrees that such Batch of Client Product is Defective Product and determines that the cause of nonconformity is attributable to Catalent's negligence or willful misconduct ("**Catalent Defective Processing**"), then Section 5.2 (D) shall apply. For avoidance of doubt, where the cause of nonconformity cannot be determined or assigned after resort to Section 5.2 (C), it shall be deemed not Catalent Defective Processing and Client shall be responsible to pay for the Batch or Batches at issue. Any nonconformity solely caused by the Client Equipment shall not be deemed Catalent Defective Processing unless such nonconformity was caused by Catalent's negligence or willful misconduct in the use of the Client Equipment.

C. Discrepant Results. If the Parties disagree as to whether the Batch of Client Product is Defective Product and/or whether the cause of the nonconformity is Catalent Defective Processing, and this disagreement is not resolved within [***] days of the receipt of Client's Exception Notice, the Parties shall cause a mutually acceptable independent third party to review records, test data and to perform comparative tests and/or analyses on samples of the alleged Defective Product and its components, including Client-supplied Materials. The independent party's results as to whether or not the Batch of Client Product is Defective Product and the cause of any nonconformity shall be final and binding. Unless otherwise agreed to by the Parties in writing, the costs associated with such testing and review shall be borne by Catalent if the Batch of Client Product is Defective Product attributable to Catalent Defective Processing, and by Client in all other circumstances.

D. Defective Processing. Catalent shall, at its option, either (A) re-Process (or if re-Processing is not permissible under cGMPs, then replace), at its cost any Batch of Defective Product attributable to Catalent Defective Processing (and Client shall be liable to pay for either the rejected Batch(es) or the replacement Batch(es), but not both), or (B) credit any payments made by Client for such rejected Batch. THE OBLIGATION OF CATALENT TO RE-PROCESS (OR REPLACE) DEFECTIVE PRODUCT IN ACCORDANCE WITH THE SPECIFICATIONS OR TO CREDIT PAYMENTS MADE BY CLIENT, IN EACH CASE, WHICH IS ATTRIBUTABLE TO CATALENT DEFECTIVE PROCESSING SHALL BE CLIENT'S SOLE AND EXCLUSIVE REMEDY UNDER THIS AGREEMENT FOR DEFECTIVE PRODUCT AND IS IN LIEU OF ANY OTHER WARRANTY, EXPRESS OR IMPLIED.

E. Supply of Material for Defective Product. In the event Catalent re-Processes (or if re-Processing is not permissible under cGMPs, then replaces) Defective Product pursuant to Section 5.4 Paragraph D only, Client shall supply, at Client's expense, Catalent with sufficient quantities of Client-supplied Materials and [***].

ARTICLE 6
DELIVERY

6.1 Delivery. Catalent shall deliver Client Product Ex Works (Incoterms 2020) the Facility upon Catalent's release of Client Product by Catalent's Quality Department. To the extent not already held by Client, title to Client Product shall transfer to Client upon Catalent's tender of delivery. In the event Catalent arranges shipping or performs similar loading or logistics services for Client at Client's written request and direction, such services are performed by Catalent at Client's expense and on Client's behalf as a convenience to Client only and do not alter the terms and limitations set forth in this Section 6.1. Catalent shall not be responsible for Client Product in transit after tender of delivery, including any cost of insurance or transport fee for Client Product, or any risk associated with transit or customs delays, storage and handling after delivery to Client.

6.2 Storage Fees. If Client fails to take delivery of any Client Product, Catalent shall transfer such Client Product to storage and title to such Client Product shall pass to Client upon transfer to storage. Catalent shall store Client Product in accordance with Applicable Laws, cGMP, and the Quality Agreement. Client shall be invoiced for the storage fees as provided in Attachment C. For Client Product released by Catalent's Quality Department, storage fees will be charged on day 21 and thereafter.

ARTICLE 7
PAYMENTS

7.1 Fees. In consideration for Catalent performing services hereunder:

A. Facility Fee. During the Term, Client shall pay to Catalent non-refundable facility fees (the "**Facility Fees**") in accordance with the following schedule:

a. $[***] on the Effective Date of the Agreement;

b. $[***] for each calendar month beginning on [***] and ending on [***]; and

c. $[***] for each calendar month beginning on [***] and ending on the last day of the month following the Commencement Date, subject to only one of the following clauses:

i. In the event the:

1. Client has met all of its responsibilities in the SRA, including but not limited to providing support to Catalent in person at the Facility by representatives of the Client Equipment Manufacturer; and

2. whereby if Catalent does not achieve the anticipated Completion Date of [***], then in the event Client is paying the monthly Facility Fee of $[***], then only such Facility Fee of $[***] shall be temporarily discontinued on that date of [***]and the monthly fee will be restarted on the first of the month in the month upon the achievement of the Completion Date. For clarity, terms herein are hereby defined by the SRA and all other Facility Fees herein under Section 7.1 A (a), and (b) are not changed by this provision and shall continue as provided therein.

ii. In the event the:

1. Catalent has met its responsibilities in the SRA with the exception of the responsibilities in the SRA that are dependent on the Client responsibilities,

2. Client has not met all of its responsibilities in the SRA, including but not limited to support to Catalent in person at the Facility by representatives of the Client Equipment Manufacturer, and

3. whereby Catalent is delayed from achieving the anticipated Completion Date of [***], then Catalent will identify the amount of additional time needed to be added to the anticipated Completion Date of [***] to recognize a new anticipated Completion Date, not to exceed 12 months from the date that Client has met all of its responsibilities in the SRA, whereby Catalent will obtain Client’s consent for the new anticipated Completion Date and such consent by Client shall not be unreasonably withheld or delayed.

4. If Catalent does not achieve the new anticipated Completion date, then in the event Client is paying the monthly Facility Fee of $[***], then only such Facility Fee of $[***] shall be temporarily discontinued on that date. The monthly fee will be restarted on the first of the month in the month upon the achievement of the Completion Date. For clarity, terms herein are hereby defined by the SRA and all other Facility Fees herein under Section 7.1 A (a), and (b) are not changed by this provision and shall continue as provided therein.

B. Pricing. Client shall pay Catalent the Unit Pricing set forth in Attachment C. Catalent shall submit an invoice to Client for such fees upon tender of delivery of Client Product as provided in Section 6.1.

C. Additional Fees. Client shall pay Catalent additional fees as provided in Attachment C and as follows:

a. Client shall pay Catalent an annual fee of $[***], [***], beginning on the first day of the month following the month during which the Commencement Date occurs, and with the payments schedule as set forth in Attachment C, Table 3 (the "**Annual Fee**").

b. Initial Serialization and Serialization Validation Fee: Client shall pay Catalent the fee for the Initial Serialization and Serialization Validation set forth in Attachment C.

c. Serialization and Maintenance Fee Services: Client shall pay Catalent the annual fees for Serialization and Maintenance Services set forth in Attachment C.

d. Commercial Data Report and Maintenance Fee.: If requested by Client, Catalent shall prepare the annual Commercial Data and Maintenance Report according to the fee set forth in Attachment C.

e. Regulatory Authority Inspection Fee: Client shall pay Catalent a Regulatory Authority Inspection Fee for each inspection by a Regulatory Authority set forth in Attachment C.

f. Mock Regulatory Authority Inspection Fee. Client shall pay Catalent the fee for each Mock Regulatory Authority Inspection as set forth in Attachment C.

g. Other Fees. Client shall pay Catalent for all other fees and expenses in accordance with the terms of this Agreement, including but not limited to Sections 6.2, 7.1 and 16.2.

7.2 Pricing Increase. All pricing and fees as shown in Attachment C and the Annual Fee, with the exception of Raw Materials (covered in Section 7.3 below), may be adjusted on an annual basis, effective on January 1 of each calendar year of this Agreement, beginning with January 1, 2023. The Unit Pricing and Annual Fee adjustments shall be equal to the Producer's Price Index **("PPI")** "Pharmaceutical Preparations Manufacturing" (Series ID: PCU325412325412), not seasonally adjusted, as published by the U.S. Department of Labor, Bureau of Statistics in September of the preceding year compared to the final number for the same month the year prior to that. .

7.3 Raw Material Pricing Increase. Price increases for Raw Materials (including those Raw Materials referenced in Section 3.2), shall be passed through to Client at the time of such price increase through an adjustment to Raw Material pricing in Attachment C on a quarterly basis. Catalent shall notify Client in writing for Raw Materials pricing increase.

7.4 Payment Terms. Payment by Client to Catalent of invoices issued by Catalent in accordance with this Agreement shall be due 30 days from date of invoice transmittal via electronic delivery. Client shall make payment in U.S. dollars, and otherwise as directed in the applicable invoice. Notwithstanding any other provision of this Agreement, if any [***] amount is not received by Catalent by its due date, then Catalent may, in addition to any other remedies available at equity or in law, (A) charge interest on the outstanding sum from the due date (both before and after any judgment) at [***] until paid in full (or, if less, the maximum amount permitted by Applicable Law); (B) suspend any further performance hereunder until such undisputed invoice amount is paid in full; (C) require payment in advance before performing any further Processing or making any further shipment of Client Product; and/or (D) terminate this Agreement for a payment breach by Client in accordance with Section 16.2 and without releasing Client from its obligations under this Agreement.

7.5 Advance Payment. Notwithstanding any other provision of this Agreement, if at any time Catalent reasonably determines, based on objective, factual information, that Client's credit is impaired or payments are not received by Catalent by its due date in Section 7.4, Catalent may require payment in advance before performing any further services or making any further shipment of Client Product. If Client shall fail, within a reasonable time, to make such required payment in advance, Catalent shall have the right, at its option, to suspend any further performance hereunder until such default is corrected, without thereby releasing Client from its obligations under this Agreement.

7.6 Taxes. All taxes, duties and other amounts assessed (excluding tax based on net income and franchise taxes) on Client-supplied Materials, services, Drug Product or Client Product prior to or upon provision or sale to Catalent or Client, as the case may be, are the responsibility of Client, and Client shall reimburse Catalent for all such taxes, duties or other expenses paid by Catalent or such sums will be added to invoices directed at Client, where applicable. If any deduction or withholding in respect of tax or otherwise is required by law to be made from any of the sums payable hereunder, Client shall be obliged to pay to Catalent such greater sum as will leave Catalent, after deduction or withholding as is required to be made, with the same amount as it would have been entitled to receive in the absence of any such requirement to make a deduction or withholding.

7.7 Client and Third Party Expenses. Except as may be expressly covered by Product Maintenance Services, Client shall be responsible for [***]% of its own and all third-party expenses associated with the development, Regulatory Approvals and commercialization of Client Product, including regulatory filings and post-approval marketing studies.

ARTICLE 8
CHANGES TO SPECIFICATIONS

All Specifications and any changes thereto agreed to by the Parties from time to time shall be in writing, dated and signed by an authorized representative of each of the Parties. No change in the Specifications shall be implemented by Catalent, whether requested by Client or requested or required by any Regulatory Authority, until the Parties have agreed in writing to such change, the implementation date of such change, and any increase or decrease in costs, expenses or fees associated with such change (including any change to Unit Pricing necessitated by such change). Catalent shall respond promptly to any request made by Client for a change in the Specifications, and both Parties shall use commercially reasonable and good faith efforts to agree to the terms of such change in a commercially reasonable and timely manner. As soon as possible after a request is made for any change in Specifications, Catalent shall notify Client in writing of the increase or decrease in costs associated with such change and shall provide such supporting documentation as Client may reasonably require. Unless otherwise agreed by the Parties in writing, Client shall pay all costs associated with such agreed upon changes. If there is a conflict between the terms of this Agreement and the terms of the Specifications, this Agreement shall control. Catalent reserves the right to postpone effecting changes to the Specifications until such time as the Parties agree to and execute the required written amendment.

ARTICLE 9
RECORDS; REGULATORY MATTERS

9.1 Recordkeeping. Catalent shall maintain materially complete and accurate Batch Records, Batch-related documentation, laboratory data, reports and other technical records relating to Processing in accordance with Catalent standard operating procedures. Such information shall be maintained for a period of at least 3 years from the relevant finished Client Product expiration date or longer if required under Applicable Laws or the Quality Agreement.

9.2 Regulatory Compliance. Catalent shall obtain and maintain all permits and licenses (including but not limited to all appropriate DEA licenses) with respect to general Facility operations required by any Regulatory Authority in the jurisdiction in which Catalent Processes Client-supplied Materials. Client shall obtain and maintain all other Regulatory Approvals, authorizations and certificates, including those necessary for Catalent to commence Processing on behalf of Client. Client shall reimburse Catalent for any payments Catalent is required to make to any Regulatory Authority pursuant to Applicable Laws that are specifically attributable to Catalent's processing, filling, packaging, storing or testing of Client's Product and Client-supplied Materials at the Facility. Client shall not identify Catalent in any regulatory filing or submission without Catalent's prior written consent. Such consent shall not be unreasonably withheld and shall be memorialized in a writing signed by authorized representatives of both Parties. Upon written request, Client shall provide Catalent with a copy of any Regulatory Approvals required to distribute, market and sell Client Product in the Territory. During the Term, Catalent will assist Client with all regulatory matters relating to Processing, at Client's request and expense. The Parties intend and commit to cooperate to allow each Party to satisfy its obligations under Applicable Laws relating to Processing under this Agreement.

9.3 Governmental Inspections and Requests. Catalent shall promptly advise Client in writing if an authorized agent of any Regulatory Authority notifies Catalent that it intends to or does visit the Facility for the purpose of reviewing the Processing or inspecting the Facility which may affect Client Product. Upon request, Catalent shall provide Client with a copy of any report issued by such Regulatory Authority received by Catalent following such visit, redacted as appropriate to protect any confidential information of Catalent and Catalent's other customers. Client acknowledges that it may not direct the manner in which Catalent fulfills its obligations to permit inspection by and to communicate with Regulatory Authorities. . Client shall reimburse Catalent for all reasonable and documented costs associated with inspections by Regulatory Authorities that are specifically attributable to the Client Product.

9.4 Client Facility Audits. During the Term, Client's Representatives shall be granted access upon at least [***] business days' prior notice, at reasonable times during regular business hours, to (A) the portion of the Facility where Catalent performs Processing, (B) relevant personnel involved in Processing and (C) Processing records described in Section 9.1, in each case solely for the purpose of verifying that Catalent is Processing in accordance with cGMPs, the Specifications and the Product master Batch Records and this Agreement. Client may not conduct an audit under this Section 9.4 more than [***] during any calendar year; *provided*, that additional inspections may be conducted in the event there is a material quality or compliance issue concerning the Client Product or its Processing. Client's Quality Assurance Manager will arrange Client audits with Catalent Quality Management. Audits shall be designed to minimize disruption of operations at the Facility. Client's Representatives that are not employees of Client, shall be required to sign Catalent's standard visitor confidentiality agreement prior to being allowed access to the Facility. Such Representatives shall comply with the Facility's rules and regulations. Client shall indemnify and hold harmless Catalent for any action or activity of such Representatives in violation of this Section 9.4 while on Catalent's premises.

9.5 Virtual Inspections or Audits. Inspections by Regulatory Authorities under Section 9.3 or Client Facility audits under Section 9.4 may be conducted by live and/or pre-recorded (as may be applicable) video and audio streaming sessions from a Facility using (i) integrated wearable "Smart Glasses" or other technologies employed by Catalent in order to facilitate remote site visits, and/or (ii) a set of related applications and software (collectively, the "**Virtual Technology**") to facilitate telepresence between Facility personnel and Regulatory Authorities or Client ("**VPP Services**"). Catalent has the right to change, modify, add to, or discontinue any feature of the VPP Services at any time, with prior notification to Client. Catalent shall provide access to live video streaming sessions via a web portal URL. Users of the Virtual Technology shall be responsible for maintaining the confidentiality of passwords and for installing anti-virus software and related protections applicable to the Virtual Technology being employed. Client may not record, by any technology or other means, any of the live video streaming sessions, or other data, information, or activities made available via the VPP Services.

9.6 Recall. If Catalent believes a recall, field alert, Client Product withdrawal or field correction ("**Recall**") may be necessary with respect to any Client Product supplied under this Agreement, Catalent shall promptly notify Client of such belief in writing. Catalent will not act to initiate a Recall without the express prior written approval of Client, unless otherwise required by Applicable Laws. If Client believes a Recall may be necessary with respect to any Client Product supplied under this Agreement, Client shall promptly notify Catalent of such belief in writing, and Catalent shall provide all commercially reasonable cooperation and assistance to Client. Client shall provide Catalent with an advance copy of any proposed submission to a Regulatory Authority in respect of any Recall, and shall consider in good faith any comments from Catalent as they relate to Processing. The cost of any Recall shall be borne by Client, and Client shall reimburse Catalent for expenses reasonably incurred in connection with any Recall at Client's request, in each case unless such Recall is caused solely by Catalent's breach of its obligations under this Agreement, violation of Applicable Laws or its negligence or willful misconduct, then such cost shall be borne solely by Catalent. For purposes hereof, such cost shall be limited to reasonable, actual and documented administrative costs incurred by Client for such Recall and replacement of the Client Product subject to Recall in accordance with Article 5.

9.7 Quality Agreement. The Parties shall negotiate in good faith and enter into the Quality Agreement. The Quality Agreement shall in no way determine liability or financial responsibility of the Parties for the responsibilities set forth therein. In the event of a conflict between any of the provisions of this Agreement and the Quality Agreement with respect to quality-related activities, including compliance with cGMP, the provisions of the Quality Agreement shall govern. In the event of a conflict between any of the provisions of this Agreement and the Quality Agreement with respect to any commercial matters, including allocation of risk, liability and financial responsibility, the provisions of this Agreement shall govern.

ARTICLE 10
CONFIDENTIALITY AND NON-USE

10.1 Definition. As used in this Agreement, the term "**Confidential Information**" means all information furnished by or on behalf of Catalent or Client (the "**Discloser**"), its Affiliates or any of its or their respective Representatives, to the other Party (the "**Recipient**"), its Affiliates or any of its or their respective Representatives, in connection with the subject matter of this Agreement on or after the Effective Date and furnished in any form, including written, verbal, visual, electronic or in any other media or manner and information acquired by observation or otherwise during any site visit at the other party's facility. Confidential Information includes, but is not limited to, all proprietary technologies, know-how, trade secrets, discoveries, inventions and any other intellectual property (whether or not patented), analyses, compilations, business or technical information and other materials prepared by the Recipient, its Affiliates, or any of its or their respective Representatives, containing or based in whole or in part on any Confidential Information of the Discloser, its Affiliates or any of its or their respective Representatives. Confidential Information also includes the existence of this Agreement and its terms.

10.2 Exclusions. Notwithstanding Section 10.2, Confidential Information does not include information that (A) is or becomes generally available to the public or within the industry to which such information relates; (B) was known to the Recipient, without restriction, and was not subject to a prior existing confidentiality agreement or similar agreement between the Parties, at the time of disclosure as evidenced by the Recipient's written records; (C) becomes available to the Recipient on a non-confidential basis from a source that, to the Recipient's knowledge, is entitled to disclose it on a non-confidential basis; (D) was independently developed by or for the Recipient without use of or reliance upon the Confidential Information of the Discloser as evidenced by the written records of the Recipient.

10.3 Mutual Obligation. The Recipient agrees that it will not use the Discloser's Confidential Information except in connection with the performance of its obligations hereunder and will not disclose, without the prior written consent of the Discloser, Confidential Information of the Discloser to any third party, except that the Recipient may disclose the Discloser's Confidential Information to any of its Affiliates and its or their respective Representatives that (A) need to know such Confidential Information for the purpose of performing under this Agreement, (B) are advised of the contents of this Article and (C) are bound to the Recipient by obligations of confidentiality at least as restrictive as the terms of this Article. Each party shall be responsible for any breach of this Article by its Affiliates or any of its or their respective Representatives. The Recipient will protect the Discloser's Confidential Information from unauthorized use, access or disclosure in the same manner as the Recipient protects its own Confidential Information of a similar nature and with no less than reasonable care.

10.4 Permitted Disclosure. The Recipient may disclose the Discloser's Confidential Information to the extent required by law, regulation or judicial or administrative process; *provided*, that prior to making any such legally required disclosure, the Recipient shall, if legally allowed, give the Discloser as much prior written notice of the requirement for, and contents of, such disclosure as is practicable under the circumstances, and before making any such disclosure, the Recipient will reasonably cooperate, at Discloser's sole cost and expense, with the Discloser's efforts to limit or avoid such disclosure and/or to seek a protective order, confidential treatment or other available remedy. Any such disclosure, however, shall not relieve the Recipient of its obligations contained herein.

10.5 Securities Filings. Each Party acknowledges and agrees that the other Party may be required under Applicable Law to submit this Agreement (including for clarity, the Exhibits and Schedules hereto) to the United States Securities and Exchange Commission (the "SEC") or any other securities exchange and if a Party does submit this Agreement to the SEC or any other securities exchange, such Party shall consult with the other Party with respect to the preparation and submission of, a confidential treatment request for this Agreement and/or redacted sections of the Agreement. If a Party is required by Applicable Law to make a disclosure of the terms of this Agreement in a filing with or other submission to the SEC or any other securities exchange or otherwise to comply with Applicable Law, and (i) such Party has provided copies of the disclosure to the other Party as far in advance of such filing or other disclosure as is reasonably practicable under the circumstances, (ii) such Party has promptly notified the other Party in writing of such requirement and any respective timing constraints, and (iii) such Party has given the other Party a reasonable time under the circumstances from the date of notice by such Party of the required disclosure to comment upon, request confidential treatment or approve such disclosure, request redacted sections, then such Party will have the right to make such public disclosure at the time and in the manner reasonably determined by its counsel to be required by Applicable Law.

10.6 No Implied License. Except as expressly set forth in Article 11, (A) the Discloser is and shall remain the exclusive owner of its Confidential Information and all patent, copyright, trade secret, trademark and other intellectual property rights therein, and (B) no license or conveyance of any such rights to the Recipient is granted or implied under this Agreement.

10.7 Return of Confidential Information. Upon expiration or termination of this Agreement, the Recipient will (and will cause its Affiliates and its and their respective Representatives to) cease its use and, upon written request, within [***] days either return or destroy (and certify as to such destruction) all Confidential Information of the Discloser, including any copies thereof, except for a single copy which may be retained for the sole purpose of ensuring compliance with its obligations under this Agreement.

10.8 Survival. The obligations of this Article will terminate 5 years from the expiration or termination of this Agreement except with respect to trade secrets, for which the obligations of this Article 10 will continue for so long as such information remains a trade secret under applicable law.

ARTICLE 11
INTELLECTUAL PROPERTY

For purposes hereof, "**Background IP**" means all intellectual property and embodiments thereof owned by or licensed to Client or Catalent, respectively, as of the date hereof, or developed by Client or Catalent, respectively, other than in connection with this Agreement; "**Invention**" means any intellectual property conceived, made, generated or developed by a Party in connection with the Agreement; "**Client Inventions**" means any Invention that directly and specifically relates exclusively to the Client's Background IP, Client Equipment, Client Proprietary Process, or Client's patented or proprietary Client-supplied Materials, Drug Product or Client Product, as applicable; and "**Catalent Inventions**" means any Invention, other than a Client Invention, that relates exclusively to the Catalent's Background IP or relates generally to manufacturing, filling, processing, packaging, analyzing or testing pharmaceutical products, except for Client Proprietary Process. All of Client's Background IP and Client Inventions shall be owned solely by Client and no right therein is granted to Catalent under this Agreement except as necessary for Catalent's use in performing the Agreement. All of Catalent's Background IP and Catalent Inventions shall be owned solely by Catalent and no right therein is granted to Client under this Agreement. The Parties shall cooperate with each other to achieve the allocation of ownership rights to Inventions as described herein, and each Party shall be solely responsible for costs associated with the protection of its intellectual property.

ARTICLE 12
REPRESENTATIONS AND WARRANTIES

12.1 Catalent. Catalent represents, warrants and undertakes to Client that (A) at the time of delivery by Catalent as provided in Section 6.1, Client Product shall have been Processed in accordance with Applicable Laws and in conformance with the Specifications and shall not be adulterated, misbranded or mislabeled within the meaning of Applicable Laws, and shall have been provided in accordance with the terms and conditions of this Agreement; *provided*, that Catalent shall not be liable for defects to the extent attributable to Client-supplied Materials (including artwork, advertising and labeling); and (B) it will not in the performance of its obligations under this Agreement use the services of any person or entity debarred or suspended under 21 U.S.C. §335(a) or (b). Catalent makes no representation or warranty with respect to the Client Equipment or the capacity thereof.

12.2 Client. Client represents, warrants and undertakes to Catalent that:

A. all Client-supplied Materials shall have been produced in accordance with Applicable Laws, shall comply with all applicable Specifications for such Client-supplied Materials, shall not be adulterated, misbranded or mislabeled within the meaning of Applicable Laws, and shall have been provided in accordance with the terms and conditions of this Agreement;

B. the content of all artwork provided to Catalent shall comply with all Applicable Laws;

C. all Client Product delivered to Client by Catalent shall be held, used and disposed of by or on behalf of the Client in accordance with all Applicable Laws, and Client will otherwise comply with all Applicable Laws with respect to Client's performance under this Agreement;

D. Client will not release any Batch of Client Product if the required Certificates of Conformance indicate that such Client Product does not comply with the Specifications or if Client does not hold all necessary Regulatory Approvals to market and sell the Client Product in a given portion of the Territory;

E. Client has all necessary authority to use and to permit Catalent to use pursuant to this Agreement all intellectual property controlled by Client related to Client Product or Client-supplied Materials (including artwork) that is necessary for the Processing of the foregoing, including any copyrights, trademarks, trade secrets, patents, inventions and developments; and to Client's actual knowledge (without inquiry), as of the Effective Date, there are no patents owned by others and existing as of the Effective Date that are directly related to the Client intellectual property that is utilized with the Client Product and that would be infringed or misused by Client's performance of the Agreement;

F. the Client Equipment is capable of producing Client Product in conformance with the Specifications and Applicable Laws (including cGMP) when operated and/or conducted in accordance with the SRA, applicable batch records and cGMP; and

G. to Client's actual knowledge (without inquiry) as of the Effective Date, the Processing to be performed by Catalent in accordance with this Agreement will not violate or infringe upon any trademark, tradename, copyright, patent, trade secret, or other intellectual property or other right held by any person or entity.

12.3 Mutual Representation. Furthermore, Catalent and Client both represent, warrant and undertake that no transactions or dealings under this Agreement shall be conducted with or for an individual or entity that is designated as the target of any sanctions, restrictions or embargoes administered by the United Nations, European Union, United Kingdom, or the United States.

12.4 Limitations. THE REPRESENTATIONS AND WARRANTIES SET FORTH IN THIS ARTICLE 12 ARE THE SOLE AND EXCLUSIVE REPRESENTATIONS AND WARRANTIES MADE BY EACH PARTY TO THE OTHER PARTY, AND NEITHER PARTY MAKES ANY OTHER REPRESENTATIONS, WARRANTIES OR GUARANTEES OF ANY KIND WHATSOEVER, INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY, NON-INFRINGEMENT OR FITNESS FOR A PARTICULAR PURPOSE.

ARTICLE 13
INDEMNIFICATION

13.1 Indemnification by Catalent. Catalent shall indemnify and hold harmless Client, its Affiliates, and their respective directors, officers and employees ("**Client Indemnitees**") from and against any and all suits, claims, losses, demands, liabilities, damages, costs and expenses (including reasonable attorneys' fees and reasonable investigative costs) in connection with any suit, demand or action by any third party ("**Losses**") to the extent arising directly out of or resulting from (A) any breach of its representations, warranties or obligations set forth in this Agreement, including a violation of Applicable Laws by Catalent, or (B) any negligence or willful misconduct by Catalent in performing under this Agreement; in each case except to the extent that any of the foregoing arises out of or results from any Client Indemnitee's negligence, willful misconduct or breach of this Agreement.

13.2 Indemnification by Client. Client shall indemnify and hold harmless Catalent, its Affiliates, and their respective directors, officers and employees ("**Catalent Indemnitees**") from and against any and all Losses to the extent arising directly out of or resulting from (A) any breach of its representations, warranties or obligations set forth in this Agreement, (B) any manufacture, packaging, sale, promotion, marketing, distribution or use of or exposure to Client Product or Client-supplied Materials that are the subject of the Agreement, including product liability or strict liability, (C) Client's exercise of control over the Processing, to the extent that Client's instructions or directions violate Applicable Laws, (D) the conduct of any clinical trials utilizing Client Product or Drug Product, (E) any actual or alleged infringement or violation of any third party patent, trade secret, copyright, trademark or other proprietary rights by intellectual property or other information provided by Client, including Client-supplied Materials, (F) use of or exposure to Client Equipment in accordance with Applicable Laws; or (G) any negligence or willful misconduct by Client; in each case except to the extent that any of the foregoing arises out of or results from any Catalent Indemnitee's negligence, willful misconduct or breach of this Agreement. In addition, Client shall indemnify and hold harmless the Catalent Indemnitees from and against any and all Losses arising out of or resulting from any federal Regulatory Authority filings pertaining to the Client Product by or on behalf of Client or any of its Affiliates, including Losses incurred by Catalent arising from Client's filings under 21 U.S.C. 355 and/or Section 505 of the Food and Drug Act (or non-U.S. equivalents) and related claims or proceedings (including Losses associated with Catalent's obligation to respond to third party subpoenas).

13.3 Indemnification Procedures. All indemnification obligations in this Agreement are conditioned upon the indemnified Party (A) promptly notifying the indemnifying Party of any third-party claim or liability of which the indemnified Party becomes aware (including a copy of any related complaint, summons, notice or other instrument); provided, that failure to provide such notice within a reasonable period of time shall not relieve the indemnifying Party of any of its obligations hereunder except to the extent the indemnifying Party is prejudiced by such failure, (B) allowing the indemnifying Party, if the indemnifying Party so requests, to conduct and control the defense of any such claim or liability and any related settlement negotiations (at the indemnifying Party's expense), (C) cooperating with the indemnifying Party in the defense of any such claim or liability and any related settlement negotiations (at the indemnifying Party's expense) and (D) not compromising or settling any claim or liability without prior written consent of the indemnifying Party.

ARTICLE 14
LIMITATIONS OF LIABILITY

14.1 EXCEPT FOR CATALENT'S GROSS NEGLIGENCE OR WILLFUL MISCONDUCT, CATALENT SHALL HAVE NO LIABILITY UNDER THIS AGREEMENT FOR ANY AND ALL CLAIMS FOR LOST, DAMAGED OR DESTROYED CLIENT-SUPPLIED MATERIALS, WHETHER OR NOT SUCH CLIENT-SUPPLIED MATERIALS ARE INCORPORATED INTO CLIENT PRODUCT.

14.2 EXCEPT FOR CLAIMS OF BODILY INJURY OR DEATH DUE TO CATALENT'S GROSS NEGLIGENCE OR WILLFUL MISCONDUCT, CATALENT'S TOTAL LIABILITY UNDER THIS AGREEMENT SHALL IN NO EVENT EXCEED [***].

14.3 NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR INDIRECT, INCIDENTAL, SPECIAL, EXEMPLARY, PUNITIVE OR CONSEQUENTIAL DAMAGES, OR FOR LOSS OF REVENUES, PROFITS OR DATA, ARISING OUT OF SUCH PARTY'S PERFORMANCE UNDER THIS AGREEMENT, WHETHER IN CONTRACT OR IN TORT, EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES

ARTICLE 15
INSURANCE

Each Party shall, at its own cost and expense, obtain and maintain in full force and effect during the Term the following: (A) Commercial General Liability Insurance with a per-occurrence limit of not less than [***]per incident and not less than [***]in the aggregate, which can be met through the combination of primary and excess liability policies; (B) Products and Completed Operations Liability Insurance with a per-occurrence limit of not less than [***]; and (C) Workers' Compensation Insurance with statutory limits and Employers Liability Insurance with limits of not less than [***]per accident. Client shall at its own cost and expense, maintain Special Risk Property Insurance, including transit coverage, in an amount equal to the full replacement value of its property while in, or in transit to, the Facility. Each Party may self-insure all or any portion of the required insurance as long as, together with its Affiliates, its US GAAP net worth is greater than [***]or its annual EBITDA (earnings before interest, taxes, depreciation and amortization) is greater than [***]. Each required insurance policy, other than self-insurance, shall be obtained from an insurance carrier with an [***]rating of at least [***]. If any of the required policies of insurance are written on a claims made basis, such policies shall be maintained throughout the Term and for a period of at least [***]thereafter. Each Party shall obtain a waiver of subrogation clause from its property insurance carriers in favor of the other Party. Each Party shall be named as an additional insured within the other Party's products liability insurance policies; provided, that such additional insured status will apply solely to the extent of the insured Party's indemnity obligations under this Agreement. Such waivers of subrogation and additional insured status obligations will operate the same whether insurance is carried through third parties or self-insured. Upon the other Party's written request from time to time, each Party shall promptly furnish to the other Party a certificate of insurance or other evidence of the required insurance.

ARTICLE 16
TERM AND TERMINATION

16.1 Term. This Agreement shall commence on the Effective Date and shall continue until the end of the 5th Contract Year, unless earlier terminated in accordance with Section 16.2 (as this term may be extended in accordance with this Section 16.1, the "**Term**") or if later, until the fulfillment of all Purchase Orders. The Term shall automatically be extended for successive 2-year periods, unless and until one Party gives the other Party at least 24 months' prior written notice of its desire to terminate as of the end of the then-current Term. In the event Client divests, sells, assigns, licenses or transfers, the partial or entire right, title and interest to the Drug Product, or Client Product to any third party, together with certain supply rights and obligations of Catalent under this Agreement pursuant to a written agreement between Client and the third party ("**Transfer**"), then this Agreement shall be partially or entirely assigned, as applicable, to the third party for each such Drug Product or Client Product Transfer as of a date specific after the Transfer ("**Transfer Date**") and the Assignment and Transfer Agreement in Attachment G shall be executed no later than within [***] days from the Transfer. Any partial Transfer does not terminate this Agreement and the fees in Table 6 shall apply.

16.2 Termination. This Agreement may be terminated as follows:

A. by either Party, if the other Party files a petition in bankruptcy, or enters into an agreement with its creditors, or applies for or consents to the appointment of a receiver, administrative receiver, trustee or administrator, or makes an assignment for the benefit of creditors, or suffers or permits the entry of any order adjudicating it to be bankrupt or insolvent and such order is not discharged within [***] days, or takes any equivalent or similar action in consequence of debt in any jurisdiction; or;

B. by either Party by delivering written notice of termination to the other Party, if the other Party materially breaches any of the provisions of this Agreement and such breach is not cured within [***] days after the giving of written notice delivered by the non-breaching Party describing the breach and requiring the breach to be remedied; *provided*, that in the case of a failure of Client to make payment amounts in accordance with the terms of this Agreement, Catalent may terminate this Agreement by delivering written notice of termination to Client, if such undisputed payment amounts are not paid within [***] days of the date of Client's receipt of written notice of such non-payment from Catalent.

16.3 Effect of Termination. Expiration or termination of this Agreement shall be without prejudice to any rights or obligations that accrued to the benefit of either Party prior to such expiration or termination. In the event of a termination of this Agreement:

A. Catalent shall promptly return to Client, at Client's expense and direction, any remaining inventory of Client Product, Drug Product and Client-supplied Materials; *provided*, that, in the case of Client Product, all outstanding invoice amounts under this Agreement have been paid in full;

B. Client shall pay Catalent for all unused Raw Materials in accordance with Section 3.2 (C); and

C. Client shall pay Catalent all outstanding invoiced amounts under this Agreement, plus, upon receipt of invoice therefore, for (i) any Client Product that has been delivered to Client pursuant to Purchase Orders but not yet invoiced, (ii) any Client Product Processed pursuant to Purchase Orders that has been completed but not yet delivered, and (iii) in the event that this Agreement is terminated for any reason other than by Client pursuant to Section 16.2(A), or (B), all Client Product in process of being Processed pursuant to Purchase Orders (or, alternatively, Client may instruct Catalent to complete such work in process, and the resulting completed Client Product shall be governed by the foregoing clause 16.3 (C)(ii)); provided that all such Client Product or Client Product in process of being Processed shall be delivered to Client upon payment of such invoiced amounts.

D. In the event that Catalent terminates this Agreement pursuant to Sections 16.2 (A) or 16.2(B), Client shall pay Catalent (i) for all costs and expenses reasonably incurred by Catalent, and for all non-cancellable commitments made by Catalent, pursuant to Catalent's performance in accordance with this Agreement, so long as such costs, expenses or commitments were made by Catalent consistent with Client's Rolling Forecast and its most recent Firm Commitment; and (ii) if owing, the Annual Fee due to Catalent for the Contract Year in which the Agreement is terminated. In the event that Client terminates this Agreement pursuant to Sections 16.2 (A) or 16.2(B), Client shall not be responsible for paying [***].

E. In the event that this Agreement is terminated for any reason other than by Client pursuant to Section 16.2(A), or (B), Client shall pay Catalent [***].

16.4 Client Equipment. Client shall remove the Client Equipment, at Client's cost, within [***] days of any expiration or termination of this Agreement. In the event the Client Equipment is not removed as provided herein, within [***] days of any expiration or termination, then Catalent may charge Client [***]

16.5 Survival. The rights and obligations of the Parties shall continue under Articles 11 (Intellectual Property), 13 (Indemnification), 14 (Limitations of Liability), 17 (Notice), 18 (Miscellaneous); under Articles 10 (Confidentiality and Non-Use) and 15 (Insurance), in each case to the extent expressly stated therein; and under Sections 7.4 (Payment Terms), 7.6 (Taxes), 7.7 (Client and Third Party Expenses), 9.1 (Recordkeeping), 9.6 (Recall), 12.4 (Limitations), 16.3 (Effect of Termination) and 16.5 (Survival), in each case in accordance with their respective terms if applicable, notwithstanding expiration or termination of this Agreement.

ARTICLE 17
NOTICE

All notices and other communications hereunder shall be in writing and shall be deemed given: (A) when delivered personally or by hand; (B) when delivered by facsimile transmission (receipt verified); (C) when received or refused, if sent by registered or certified mail (return receipt requested), postage prepaid; or (D) when delivered if sent by express courier service; in each case to the parties at the following addresses (or at such other address for a party as shall be specified by like notice in accordance with this Article 17; *provided*, that notices of a change of address shall be effective only upon receipt thereof):

To Client:	AcelRx Pharmaceuticals, Inc. 351 Galveston Drive Redwood City, California 94063 Attn: Chief Engineering Officer Facsimile: +1 (650) 216-6500
With a copy to:	AcelRx Pharmaceuticals, Inc. 351 Galveston Drive Redwood City, California 94063 Attn: Legal Department Facsimile: +1 (650) 216-6500 Email: [***]
To Catalent:	Catalent CTS, LLC 10245 Hickman Mills Drive Kansas City, MO 64137 USA Attn: General Manager Facsimile: +1 (816) 767-7312
With a copy to:	Catalent Pharma Solutions, LLC 14 Schoolhouse Road Somerset, NJ 08873 Attn: General Counsel (Legal Department) Facsimile: +1 (732) 537-6491 Email: [***]

ARTICLE 18
MISCELLANEOUS

18.1 Entire Agreement; Amendments. This Agreement, together with the Quality Agreement, constitutes the entire understanding between the Parties, and supersedes any other contracts, agreements or understandings (oral or written) of the Parties, with respect to the subject matter hereof. For the avoidance of doubt, this Agreement does not supersede any existing generally applicable confidentiality agreement between the Parties as it relates to time periods prior to the date hereof or to business dealings not covered by this Agreement. No term of this Agreement may be amended except upon written agreement of both Parties, unless otherwise expressly provided in this Agreement.

18.2 Captions; Certain Conventions. The captions in this Agreement are for convenience only and are not to be interpreted or construed as a substantive part of this Agreement. Unless otherwise expressly provided herein or the context of this Agreement otherwise requires, (A) words of any gender include each other gender, (B) words such as “herein”, “hereof”, and “hereunder” refer to this Agreement as a whole and not merely to the particular provision in which such words appear, (C) words using the singular shall include the plural, and vice versa, (D) the words “include(s)” and “including” shall be deemed to be followed by the phrase “but not limited to”, “without limitation” or words of similar import, (E) the word “or” shall be deemed to include the word “and” (e.g., “and/or”) and (F) references to “Article,” “Section,” “subsection,” “clause” or other subdivision, or to an attachment or other appendix, without reference to a document are to the specified provision or attachment of this Agreement. This Agreement shall be construed as if it were drafted jointly by the Parties.

18.3 Further Assurances. Each Party will execute, acknowledge and deliver such further instruments and will take all such other incidental acts as may be reasonably necessary or appropriate to carry out the purpose and intent of this Agreement.

18.4 No Waiver. Failure by either Party to insist upon strict compliance with any term of this Agreement in any one or more instances will not be deemed to be a waiver of its rights to insist upon such strict compliance with respect to any subsequent failure.

18.5 Severability. If any term of this Agreement is declared invalid or unenforceable by a court or other body of competent jurisdiction, the remaining terms of this Agreement will continue in full force and effect.

18.6 Independent Contractors. The relationship of the Parties is that of independent contractors, and neither Party will incur any debts or make any commitments for the other Party except to the extent expressly provided in this Agreement. Nothing in this Agreement is intended to create or will be construed as creating between the Parties the relationship of joint ventures, co-partners, employer/employee or principal and agent. Neither Party shall have any responsibility for the hiring, termination or compensation of the other Party's employees or contractors or for any employee benefits of any such employee or contractor.

18.7 Successors and Assigns. This Agreement will be binding upon and inure to the benefit of the Parties, their successors and permitted assigns. Neither Party may assign this Agreement, in whole or in part, without the prior written consent of the other Party, except that either Party may, without the other Party's consent (but subject to prior written notice), assign this Agreement in its entirety to an Affiliate or to a successor to substantially all of the business or assets of the assigning Party or the assigning Party's business unit responsible for performance under this Agreement.

18.8 No Third Party Beneficiaries. This Agreement shall not confer any rights or remedies upon any person or entity other than the Parties named herein and their respective successors and permitted assigns.

18.9 Governing Law. This Agreement shall be governed by and construed under the laws of the State of Delaware, USA, excluding its conflicts of law provisions. The United Nations Convention on Contracts for the International Sale of Goods shall not apply to this Agreement.

18.10 Alternative Dispute Resolution. Any dispute that arises between the Parties in connection with this Agreement shall be discussed by the Parties in a good faith effort to resolve such dispute. In the event that such discussions are not successful, such dispute shall be submitted to a senior executive of each of the Parties (the "**Executives**") for consideration, discussion and resolution. If such Executives cannot reach a resolution of the dispute within a reasonable time (but in no case more than [***] days), then such dispute shall be finally resolved by confidential, binding alternate dispute resolution in accordance with the then existing commercial arbitration rules of The CPR Institute for Conflict and Dispute Resolution, 30 East 33rd Street, 6th Floor, New York, NY 10016. If either Party intends to commence binding alternate dispute resolution of such dispute, such Party shall provide written notice to the other Party informing the other Party of such intention and the issues to be resolved. The location of the arbitration shall be New York, New York.

18.11 Prevailing Party. In any dispute resolution proceeding between the Parties in connection with this Agreement, the prevailing Party will be entitled to recover its reasonable attorney's fees and costs in such proceeding from the other Party.

18.12 Publicity. Neither Party will make any press release or other public disclosure regarding this Agreement or its terms without the other Party's express prior written consent (such consent not to be unreasonably withheld), except as required under Applicable Laws, by any governmental agency or by the rules of any stock exchange on which the securities of the disclosing Party are listed, in which case the Party required to make the press release or public disclosure shall use diligent and commercially reasonable efforts to obtain the written approval of the other Party as to the form, nature and extent of the press release or public disclosure prior to issuing the press release or making the public disclosure.

18.13 Right to Dispose and Settle. If Catalent requests in writing from Client direction with respect to disposal of any inventories of Client Product, Client-supplied Materials, Client Equipment, samples or other items belonging to Client and is unable to obtain a response from Client within a reasonable time period after confirming that Client received such request and thereafter making reasonable efforts to do so, Catalent shall be entitled in its sole discretion to (A) dispose of all such items and (B) set off any and all amounts due to Catalent or any of its Affiliates from Client against any credits Client may hold with Catalent or any of its Affiliates.

18.14 Force Majeure. Except as to payments required under this Agreement, neither Party shall be liable in damages for, nor shall this Agreement be terminable or cancelable by reason of any delay or default in such Party's performance hereunder if such default or delay is caused by events beyond such Party's reasonable control, including acts of God or any, law or regulation or other action or failure to act of any government or agency thereof, terrorist events, armed hostilities, strikes or lockouts, factory shutdowns, embargoes, wars or insurrection, riots, civil commotion, labor disturbances, epidemic, pandemic, destruction of production facilities or materials by earthquakes, fires, floods or weather, or failure of suppliers, vendors, public utilities or common carriers or shortages in transportation; *provided*, that the affected Party seeking relief under this Section 18.14 shall promptly notify the other Party in writing of such cause(s) beyond such affected Party's reasonable control and the expected duration of such Party's non-performance hereunder. The Party that invokes this Section 18.14 shall use diligent and commercially reasonable efforts to reinstate performance of its ongoing obligations to the other Party as soon as practicable. If the cause(s) continue unabated for [***] consecutive days, then both Parties shall meet to discuss and negotiate in good faith what modifications to this Agreement should result from such cause(s).

18.15 Counterparts. This Agreement may be executed in one or more counterparts, each of which will be deemed an original but all of which together will constitute one and the same instrument. Any photocopy, facsimile or electronic reproduction of the executed Agreement or signature by electronic signature means shall constitute an original.

[Signature page follows]

IN WITNESS WHEREOF, the Parties have caused their respective duly authorized representatives to execute this Agreement as of the Effective Date.

Catalent Pharma Solutions, LLC		**AcelRx Pharmaceuticals, Inc.**	
By:	/s/ Ricci Whitlow	By:	/s/ Vincent J. Angotti
Name:	Ricci Whitlow	Name:	Vince J. Angotti
Title:	President, CSS	Title:	CEO

Lists of Exhibits and Schedules

Attachment A -	N/A
Attachment B -	Specifications
Attachment C -	Unit Pricing, Raw Material Pricing Breakout, Annual Fee, Additional Fees, Storage Fees, Asset Transfer
Attachment D -	Client Equipment, Client Equipment Consumables, Client Equipment Spare Parts
Attachment E -	Quality Agreement
Attachment F -	Bailee Letter
Attachment G -	(Partial) Assignment Agreement (Form) (Partial as applicable)

Exhibit 31.1

CERTIFICATION

I, Vincent J. Angotti, certify that:

1. I have reviewed this quarterly report on Form 10-Q of AcelRx Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 16, 2021

/s/ Vincent J. Angotti
Vincent J. Angotti
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, Raffi Asadorian, certify that:

1. I have reviewed this quarterly report on Form 10-Q of AcelRx Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 16, 2021

/s/ Raffi Asadorian
Raffi Asadorian
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Vincent J. Angotti, Chief Executive Officer of AcelRx Pharmaceuticals, Inc. (the "Company"), and Raffi Asadorian, Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended June 30, 2021, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report") fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act, and

2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

In Witness Whereof, the undersigned has set his hands hereto as of the 16th day of August 2021.

/s/ Vincent J. Angotti
Vincent J. Angotti
Chief Executive Officer

/s/ Raffi Asadorian
Raffi Asadorian
Chief Financial Officer

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of AcelRx Pharmaceuticals, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.